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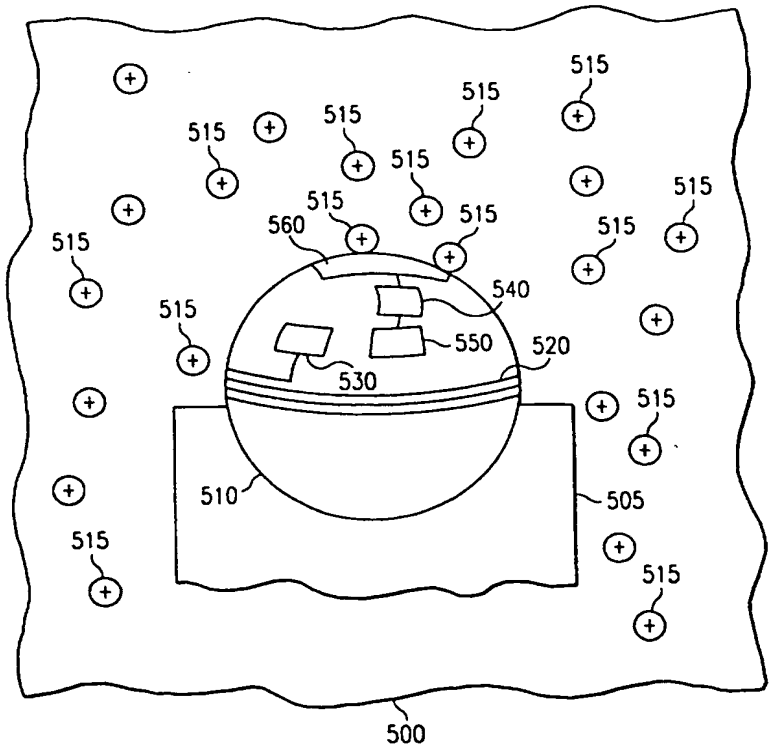
(54) Title: SPHERICALLY-SHAPED BIOMEDICAL IC

(57) Abstract

The present invention provides a biomedical semiconductor integrated circuit device that is spherical in shape (ball) for implantation in the biological medium (500) to be monitored or affected. The spherical-shaped IC (510) may include transducers (560) to perform a wide variety of instrumentation, monitoring and test or treatment regimes. The curvature of the semiconductor ball (510) allows for fabrication of more than one sensor on the ball to provide for three dimensional physiological parameter (515) monitoring. The ball (510) can be adapted to body tissue and/or tissue prosthetics, artificial organs, and biomedical implements by fixation, floatation or attachment to a catheter (505). More than one ball having one or more sensors can be used. Powering of the ball can be provided by electromagnetic coupling or on-board battery sourcing (battery ball).



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SPHERICALLY-SHAPED BIOMEDICAL IC

TECHNICAL FIELD OF THE INVENTION

The present disclosure is directed to a biomedical device and more particularly to a spherical-shaped or an ovoid-shaped or an ellipsoid-shaped biomedical integrated circuit having transducers associated therewith configured as sensors or actuators or sensors and actuators in combination for use both invasively and non-invasively to perform a wide variety of biomedical instrumentation, monitoring and treatment applications.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/110,107 entitled "SPHERICALLY-SHAPED BIOMEDICAL IC," filed November 25, 1998 (Atty. Dkt. No. BASI-24,784); and is related to co-pending U.S. Patent Application Serial No. 09/321,862 (Atty. Dkt. No. BASI-24,631) entitled "X-RAY IMAGING APPARATUS USING SPHERICAL SEMICONDUCTOR DETECTORS," filed on May 28, 1999; U.S. Patent Application Serial No. 09/323,585 (Atty. Dkt. No. BASI-24,635) entitled "IMPLANTABLE EPICARDIAL ELECTRODE," filed on June 2, 1999; U.S. Provisional Patent Application Serial No. 60/137,071 (Atty. Dkt. No. BASI-24,658) entitled "GLUCOSE SENSOR," filed on June 2, 1999; U.S. Provisional Patent Application Serial No. 60/110,106 (Atty. Dkt. No. BASI-24,783) entitled "INTRALUMINAL MONITORING SYSTEM," filed on November 25, 1998; U.S. Provisional Patent Application Serial No. 60/110,103 (Atty. Dkt. No. BASI-24,785) entitled "MINIATURE SPHERICAL-SHAPED SEMICONDUCTOR WITH TRANSDUCER," filed November 25,

1998; U.S. Provisional Patent Application Serial No. 60/11,041 (Atty. Dkt. BASI-24,787) entitled "INTERNAL THERMOMETER," filed November 25, 1998; U.S. Provisional Patent Application Serial No. 60/11,035 (Atty. Dkt. No. BASI-24,788) entitled "METHOD OF AND SYSTEM FOR IDENTIFYING MEDICAL PRODUCTS," filed November 25, 1998; and U.S. Provisional Patent Application No. 60/11,040 (Atty. Dkt. No. BASI-24,789) entitled "MONITOR FOR INTERVENTIONAL PROCEDURES," filed November 25, 1998.

BACKGROUND OF THE INVENTION

Invasive and non-invasive electronic biomedical devices are known in the art. Some examples of such devices are described in The Electronic Engineers' Handbook, Fink Christianson, McGraw Hill (1982). Others can be found in The Biomedical Engineering Handbook, CRC Press (1995). However, prior art devices are generally limited in operability and versatility for use in biomedical applications by their flat, rectangular shape. In addition, the size required for fabrication of semiconductor integrated circuits using flat surface technology limits their ability to be used for complicated biomedical instruments.

SUMMARY OF THE INVENTION

The invention disclosed and claimed herein, in one aspect thereof, comprises a miniature biomedical semiconductor integrated circuit device that is spherical in shape and is referred to herein as a ball. The smallness and the RF capability of the ball allow the device to be adapted to many different biomedical applications. In one embodiment, an implantable monitor circuit is provided comprising a substrate having a portion thereof configured with an arcuate surface and a transducer disposed on the arcuate portion for coupling a signal representative of a desired stimulus or of a quantitative condition of an adjacent medium wherein the substrate is capable of being disposed within a desired portion of a biological medium.

In one aspect, the transducer is configured as a sensor for sensing a quantitative condition of the adjacent medium and generating an electrical signal representative thereof. In another aspect, the transducer is configured as an actuator for introducing an effect into an adjacent medium responsive to an electrical signal representing a desired stimulus to the adjacent medium.

In another aspect, one or more sensors are fabricated on the surface of the semiconductor ball for detecting pH or the presence of other ions, oxygen, hemoglobin, enzymes and other proteins, carbohydrates, lipids, and phospholipids; for detecting temperature, position, motion, distance, velocity, acceleration, force, pressure, fluid flow; and/or for detecting electrical, magnetic, sound, light, or other physiological parameters. The curvature of the semiconductor ball, which may be spherical or ovoid or ellipsoid-shaped, allows for fabrication of more than one sensor on the semiconductor ball to provide for three dimensional physiological parameter monitoring and for multiple parameter monitoring.

In another aspect, the semiconductor ball can be adapted to body tissue and/or tissue prosthetic devices, artificial and hybrid organs, and biomedical implements applied invasively and noninvasively. The shape of the device can be spherical, ovoid, or elliptical. Adaptation of the semiconductor ball to the body tissue can be by fixation, floatation or other means.

In another aspect, a semiconductor ball having one or more sensors and/or actuators can be operable for biosensing, physiological monitoring; diagnostics; imaging; electronic patient monitoring; interventional radiology and cardiology procedures, stimulation, drug delivery and

other therapies and treatment; prosthetics; physiological and surgical robotic systems; computerized physiological data processing and tracking; virtual reality-based simulation of medical procedures, and other invasive and non-invasive biomedical applications.

In another aspect having more than one semiconductor ball with one or more of the balls provided with one or more sensors, the balls are clustered together to form the biomedical device or are otherwise associated with a separate biomedical device to provide expanded three dimensional instrumentation and/or monitoring.

The ball may consist of silicon or other nonorganic semiconductor material, or may consist of high density polymer organic material. Powering of the semiconductor or polymer organic material ball can be provided by electromagnetic coupling; on-board battery sourcing (ball battery); or other energy sourcing apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and the advantages thereof, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

FIGURE 1 illustrates a perspective view of a spherical-shaped biomedical device of the present disclosure;

FIGURE 2 illustrates a functional diagram of a spherical-shaped device of the present disclosure and a remote station for interrogating the disclosed embodiment and receiving information transmitted from the device;

FIGURE 3 illustrates a perspective view of the device of FIGURE 1 adapted for measuring ion concentration in a fluid;

FIGURE 4 illustrates a functional diagram view of an artery with a catheter containing a ball attached to the tip;

FIGURE 5a illustrates the ball device of FIGURE 4 adapted with a pH sensor and the circuitry required for conversion of the signal to radio frequency;

FIGURE 5b illustrates an exploded view of the RF transmission circuitry 50 of FIGURE 5 used to convert the signal to radio frequency;

FIGURE 5c illustrates an embodiment having a ball semiconductor IC according to the present disclosure attached to a catheter which is inserted into an artery for monitoring ion concentration;

FIGURE 6 illustrates placement of a catheter containing a pressure transducer-containing ball introduced into the intraventricular space to monitor intracerebral pressure and in another embodiment into the subarachnoid space to monitor intracerebral pressure;

FIGURE 7 illustrates position sensor ball(s) attached with tissue glue to the vocal cords in order to monitor position sense;

FIGURE 8 illustrates a stress transducer placed in normal bone to detect stress at a site near placement of a prosthetic hip replacement;

FIGURE 9 illustrates the position of radiation sensors located within the tumor and around the perimetery of the tumor;

FIGURE 10 illustrates a side elevation of a cluster of balls that may be employed as a monitor in accordance with the present disclosure;

FIGURE 11 illustrates a vertical sectional view through electrical contacts of the embodiment of FIGURE 10 taken along line 11 of FIGURE 10;

FIGURE 12 is a schematic depiction of a cluster of balls that may have application in the context of the present disclosure;

FIGURE 13 illustrates a coronary care unit in which a ball is used to detect an abnormal arrhythmia;

FIGURE 14 illustrates a functional diagram of a ball of the present disclosure with more complex robotic capability; and

FIGURE 15 illustrates one embodiment of a robotic device for delivery of medicine to a patient site using a ball of the present disclosure.

FIGURE 16 is a block diagram of a semiconductor ball with an integral transducer in combination with a radio frequency communication system in accordance with the present disclosure.

FIGURE 17 illustrates a schematic block diagram of a receiver/transmitter and a detection/power system in accordance with the present disclosure;

FIGURES 18a-18c illustrate alternative embodiments for the receiver/transmitter and the storage capacitors associated therewith of the present disclosure;

FIGURE 19 illustrates a cross-sectional diagram of the primary storage capacitor of the present disclosure;

FIGURE 20 illustrates a cross-sectional diagram of conductive terminals for interfacing with the exterior of the electrode of the present disclosure;

FIGURE 21 illustrates a perspective view of one of the semiconductor balls having antenna leads disposed thereon according to the present disclosure;

FIGURE 22 illustrates a cross-sectional diagram of the portion of the surface of the spherical IC of FIGURE 21;

FIGURE 23 illustrates a cross-sectional side view of an epicardial lead for an alternate embodiment illustrating the use of an additional capacitor and/or a battery according to the present disclosure;

FIGURE 24 illustrates a schematic block diagram of one embodiment of circuitry for utilizing a battery as the primary power source according to the present disclosure;

FIGURE 25 illustrates a pH sensitive hydrogel covalently attached to the surface of a ball semiconductor sensor according to a class of embodiments described in the present disclosure;

FIGURE 26 illustrates an alternate embodiment of a ball semiconductor sensor that has at least two osmotic pressure sensors located on the same ball sensor according to the present disclosure;

FIGURE 27 illustrates a graph indicating the volume of the hydrogel as a function of the change in pH;

FIGURE 28 illustrates a corresponding graph showing the anticipated sensed pressure as a function of pH changes, which will be proportional to graphing pressure changes as a function of glucose concentration if glucose oxidate is attached to the hydrogel;

FIGURE 29 illustrates an alternate embodiment of a ball semiconductor sensor having a well for electrochemical detection of glucose using a pH sensitive hydrogel coupled with an electrically conductive polymer;

FIGURE 30 illustrates an enlarged cross section of a portion of a spherical-shaped semiconductor device showing an example of a transducer structure in accordance with the present disclosure;

FIGURE 31 illustrates a plan view of the transducer of FIGURE 30;

FIGURE 32 is an implementation of a transducer circuit in accordance with the present disclosure;

FIGURE 33 illustrates a diagrammatic view of an X-ray source generator utilized in conjunction with a flat panel X-ray detector according to the present disclosure;

FIGURE 34 illustrates a view of a portion of the upper surface of the flat panel X-ray detector according to the present disclosure;

FIGURES 35a-35d illustrate the different configurations of spherical semiconductors according to the present disclosure and the detector array pixels disposed thereon according to the present disclosure;

FIGURE 36 illustrates a cross-sectional diagram of one of the spherical semiconductor detectors according to the present disclosure;

FIGURE 37 illustrates a detailed cross section of one of the detector pixels; and

FIGURE 38 illustrates a schematic diagram of single pixel detection circuit.

DETAILED DESCRIPTION OF THE INVENTION

1. Ball Semiconductor IC

A spherical-shaped IC has been disclosed by Applicant in U.S. Patent Number 5,955,776, issued September 21, 1999. Such a spherical-shaped IC, which may also be ovoid-shaped or ellipsoid-shaped, is also sometimes referred to herein simply as a ball, a ball semiconductor, a semiconductor ball or a ball semiconductor IC.

Many biomedical measurement and instrument functions can be performed by the ball device of the present disclosure. Conventional ICs cannot match the versatility provided by the unique spherical shape of semiconductor ball device disclosed herein.

The spherical geometry of the semiconductor ball devices disclosed herein offer a number of advantages compared to conventional semiconductor devices having a planar or two-dimensional geometry. By way of illustration, a few of these advantages include the following: a spherical device has a smooth, rounded shape which is easily implanted or injected into a biological medium and which may pass easily through a biological medium if necessary in a particular application. Further, the large surface area of a spherical device relative to its overall dimensions provides for a maximum of surface area devoted to functional regions in contact with the biological medium, such as transducers and other circuitry while maintaining a device of the smallest possible size for ease of passage through a vascular system, implantation, etc. Further, the spherical device permits disposition on a single device of transducers aligned on all three geometric axes for maximum transducer function. Moreover, the rounded, three-dimensional shape of the spherical IC permits an inductor to be wound on the surface thereof which more closely approximates the ideal cylindrical form of an inductor.

The versatility of the spherical-shaped IC further extends to all kinds of transducers, including both sensing applications as well as actuating applications and even combinations thereof. It is well known, for example, that a transducer inherently, in many cases, has the capability to either sense a condition or to actuate a condition or both, depending on how it is configured or used in a particular application. Numerous embodiments having both transduction capabilities will be described in the present disclosure. However, the examples described are

intended to be illustrative, and not limiting of the many and varied possible embodiments and alternative uses to which the inventions of the present disclosure may be applied.

2. Physiological Monitoring Applications

In one illustrative application, a ball semiconductor device is operable for monitoring a physiological condition of the body.

Referring to FIGURE 1, semiconductor ball IC 10 comprises one or more transducers fabricated on the surface of the ball 10 where it may be exposed to a portion of a biological medium in which a parameter is to be sensed or affected by an actuator. There is also an inductance coil 20, power regulator 30, processor 40 and electronics including RF transmitter 50. Transducer 60, which may be a sensor or an actuator, is coupled to processor 40 via line 52. The transducer 60, processor 40, and other circuitry on the ball 10 are powered by a power regulator 30 which provides a relatively constant DC voltage of about 3 volts to the circuits on the ball 10. A preferred power source for the semiconductor ball 10 is an inductance or power coil 20 which becomes energized by a separate nearby source (not shown) providing a varying magnetic field for inducing electric energy into power coil 20.

Alternatively, the ball IC 10 may be powered by a miniature battery (not shown) connected to the ball 10 as well as to clusters of similar balls with different functions, such as memory. The miniature battery may also be in the shape of a battery ball to accommodate a common connection scheme between adjacent balls. Preferably, such battery balls may be an electric double layer condenser formed of such materials as manganese dioxide, lithium, carbon or lithium ion, etc. Since such a battery ball provides a greater capacity energy source than radio frequency energy generated through the inductance or power coil 20, longer communication distances can be achieved.

The inductance or power coil 20 has ends 20a and 20b (not shown) that are connected by subsurface conductors (not shown) to the other circuit elements on the ball 10. It will be appreciated that the inductance or power coil 20 may have many more windings than the three windings actually shown. The signal processor 60 provides an output to a transmitter 50 that preferably radiates a radio-frequency (RF) signal to a receiver (not shown) at another location.

Both the magnetic field generator and receiver can be included in a common computer-controlled apparatus or CPU station within proximity of the ball 10 at least when its operation is required.

The inductance coil 20, power regulator 30, processor 40 (which may include an A/D converter) and electronics 50 collectively form a transponder circuit 15 disposed upon substrate 42 as shown in the functional block diagram of FIGURE 2. Inductance coil 20 is formed of a conductive path 28 which is wound on the surface of substrate 42 around the semiconductor ball 10, with non-conductive spaces 24, 26 between the windings. The inductance coil 20 is coupled with power regulator 30 and RF transmitter 50. To measure ions, for example, one embodiment ball IC 10 can have is shown in FIGURE 3 which has the same elements and numbering as the FIGURE 1 device and further includes a reference electrode 70 coupled to processor 40 via line 54 that coacts with transducer 60 to provide information on ionic activity.

FIGURE 2 further shows an interrogator device 110 comprising a power transmitter 120 for transmitting radio frequency 121 to the ball IC 10 , a CPU 130, an RF receiver 140 and may include a display 150.

Referring specifically to FIGURE 2, an embodiment is illustrated wherein sensor 60 includes a transducing element that generates an electrical signal in response to a physiological condition. Sensor 60 is conventional in construction and may be configured to be responsive for measuring any physiological condition parameter or variable of interest. Some examples of physiological conditions, parameters and variables include changes in ion concentration, pH, electrical activity (EKG, EEG), levels of glucose, proteins, lipids, carbohydrates, enzymes, hormones, hemoglobin, cell integrins, variations in temperature, pressure, position, velocity, emissions of x-rays, light, sound, infrared, changes in rhythm or frequency, and the like. Sensor 60 is conventional in construction and may include sensors to measure any physiological condition of interest. Examples of sensors are described in the *ELECTRONIC ENGINEERS HANDBOOK*, Second Edition, Fink, Christianson 1982, by McGraw-Hill, Inc.; and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995) which are incorporated herein by reference.

Generally, transponder circuitry 15 is electrically coupled to sensor 60 for receiving the sensor signals, converting the signals to digital format, analyzing the signals and transmitting

such signals to a device external to the ball IC 10 via a transmitter 50 and inductance coil 20 serving as an antenna when subjected to an interrogation signal from the interrogator device 110. The dashed line in FIGURE 2 indicates that the interrogator device 110 is external of the biological medium in which the device containing the semiconductor ball IC 10 is implanted.

In the preferred embodiment, transponder circuitry 15 comprises a processor 40, preferably connected for receiving signals from sensor 60. Processor 40 digitizes and formats such signals for transmission as a binary data stream. The binary data stream can be provided with appropriate protocol information including a unique ID for use in identifying the ball IC that is transmitting. This coding is especially advantageous where more than one ball IC is being monitored.

Inductance coil 20 is preferably formed from conductive material and may be designed to electromagnetically couple either with RF receiver 140 or power transmitter 120. The CPU 130 interrogates the RF carrier frequency signal received by RF receiver 140 to extract the physiological data and may also store the data in a computer memory (not shown). The data extracted, after processing in CPU 130 may be displayed on display 150. In addition, the circuitry in transponder 15 serves to generate power to drive the operation of the ball IC 10. The inductance coil 20 is energized by radio frequency 121 derived from the nearby power transmitter 120.

Systems that energize and interrogate remote electronic devices using electromagnetic energy and RF communication are well known. Such remote electronic devices are sometimes referred to as passive transponders. Examples are described in the following U.S. Patents: 4,345,253; 5,252,962; and 5,347,263, which are incorporated herein by reference.

In one illustrative embodiment shown in FIGURE 4, a ball 10 is used to detect the pH of blood flowing through an artery 200. As shown there, a ball 10 is attached to a catheter 100 which has been passed into an artery 200 to detect pH of blood passing through the blood vessel. The signal generated by sensor 60 is digitized by processor 40, modulated onto a carrier frequency by RF transmitter 50 and transmitted by radio waves via an antenna (not shown) outside the body as disclosed above. See the general description of ball IC of FIGUREs 1 and 2. The same general configuration can be employed to measure pressure, temperature, partial

pressured oxygen or combinations thereof by suitable applications of one or more sensing balls, on or in the vicinity of the catheter tip.

Another illustrative embodiment shown in FIGURE 5a shows a spherical IC 10 with sensor 60 and reference electrode 70 adapted for determining ion activity. The circuitry required for conversion of the sensed signal to a radio frequency signal is shown in FIGURE 5b. Sensor 60 is shown fabricated in FIGURE 5a as a silicon dioxide gate ion-sensitive FET (ISFET). Sensor 60 is preferably formed by doping the desired sensor location with p-type dopant 61, depositing n-region drain 62 and source 63, depositing Si_3NO_4 insulating layers 64, 68 and gate insulating layer 66, metallic layers 65, 67 and insulation layer 69 as shown in FIGURE 5a using semiconductor techniques disclosed in commonly assigned and U.S. Patent Number 5,955,776, issued September 21, 1999. While gate insulator layer 66 formed from Si_3NO_4 is preferred, Al_2O_3, or other material sensitive to pH can be used. Source 63 of sensor 60 is electrically coupled via line 52 to processor 40 which digitizes the sensor data. Digitized data from processor 40 is applied to RF transmitter 50 for modulation of the digitized data on a radio frequency signal using, for example, Frequency-Shift Keying (FSK) techniques. As shown in FIGURE 5b, RF transmitter 50 comprises a mixing circuit 52, first and second RF oscillators 54, 56, and an amplifier 58.

In particular, the signal from source 63 (shown in FIGURE 5a) of sensor 60 corresponding to the level of ionic activity and digitized by processor 40 is applied to one input 53 of mixing circuit 52. A first high frequency signal from RF oscillator 54 is applied to a second input 55 of mixing circuit 52, and a second low frequency signal from RF oscillator 56 is applied to a third input 57 of mixing circuit 52. The mixing circuit 52 modulates the incoming packet of digital information between a high frequency signal from RF oscillator 54 for use in generating each logic "high" bit of data in the information packet; and a low frequency signal from RF oscillator 56 for use in transmitting each logic "low" bit of data in the information packet. The resulting FSK signal is amplified by amplifier 58 and applied to coil 20 for transmission to RF receiver 140 (shown in FIGURE 2) of the remotely located receiver station 110.

Referring still to FIGURE 5a, drain 62 of sensor 60 is electrically coupled via capacitor 80 and line 54 to reference electrode 70 which is a conventional reference electrode well known

in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982), and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of these kind of electrodes can be readily adapted to a ball IC using the fabrication techniques described in U.S. Patent Application Number 5,955,776, issued September 21, 1999, referenced above. Capacitor 80 is used to smooth the signal from sensor 60 that is representative of the ionic level of activity that is applied to drain 62 of sensor 60. The performance of the ISFET can be protected from the clotting of blood, or other of the body's defenses by encapsulation of the device within a polymeric or gel coating albumin, or a "bio-coating." Examples of such encapsulation are described in the following U.S. Patents: 4,530,974 and 5,017,670 which are incorporated herein by reference. The sensor 60 shown in FIGURE 5 is readily adaptable by suitable reconfiguration to sense other physiological parameters besides pH, chemical parameters and variables as described previously and physical parameters such as pressure, movement, temperature and the like. Thus, the example described in FIGURES 5a and 5b is intended to be illustrative and to not limit the disclosed embodiment.

In applications where information regarding ionic activity or concentration is sought, one example of a sensor 60, an ion-sensitive field effect transistor ISFET, as described hereinabove, is essentially an insulated gate field effect transistor (IGFET) without its metal gate. The operation of the ISFET is similar to that of IGFET if one considers the reference electrode 70 and the electrolyte into which the semiconductor ball is placed as the modified gate. In operation, the interfacial potential of the electrolyte-insulator interface produced by the net surface charge due to the ionization and complexation with the ions in a solution will affect the channel conductance of the ISFET in the same way as the external gate voltage applied to the reference electrode. The drain current of the ISFET is therefore a function of the electrolytes in solution for a constant drain-source voltage. Various materials can be used for the gate insulators, such as SiO_2, Si_3N_4 and Al_2O_3. For pH sensors, Si_3N_4 and Al_2O_3 provide satisfactory performance. ISFET's for other ions such as K^+, Na^+, and Ca_2^+ may have a layer coated over the gate insulator of valinomysin in PVC, aluminosilicate, and dedecyl phosphonate, respectively.

In FIGURE 4, a ball 10 is shown inserted into a passage in the body by using a catheter 100. Alternatively, the ball can be attached to a guidewire, stylet, fiberoptic device or needle inserted within arteries, veins, or other smaller blood vessels located about the body. Attachment

can be by adhesive bonding or other attachment methods or devices. The ball may also be introduced into the intraventricular, epidural, and subarachnoid spaces, or even within cerebral tissue while attached to a needle, stylet, catheter, fiberoptic device or guidewire; or it may be implanted alone. In yet other embodiments, the ball semiconductor IC can be attached to a catheter, guidewire, stylet, trocar, fiberoptic device, needle or implanted alone in one or more other body cavities such as peritoneal or thoracic cavities, sinuses (for example nasopharynx, maxillary, frontal, and ethmoid), joint cavities (for example finger, wrist, shoulder, hip, knee, ankle, and toe), ocular (for example vitreous humor), otic (for example middle and inner ear, mastoid cells), gastrointestinal (for example oral cavity, pharynx, esophagus, stomach, small and large intestine, rectum, and pancreatic-biliary ducts), respiratory (for example trachea, bronchus, bronchioles, and alveoli), urogenital (for example kidney, ureter, bladder, urethra, and prostate), reproductive systems (for example vagina, cervix, uterus, fallopian tubes, and ovaries), intramuscularly and any extracellular spaces where pH is to be measured and/or detected.

In another embodiment of the present disclosure, a semiconductor ball attached to a catheter, guidewire or fiberoptic device can also be inserted within the vascular system (arteries, veins, smaller blood vessels) or implanted in tissue to monitor ion concentration of such ions as K^+, Na^+, or Cl^- or other ions within the blood or extracellular fluid. In these instances, the IC is adapted to exhibit appropriate ion-specific transduction properties to measure the ionic activity of interest.

Conventional K^+ sensors are well known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a K^+ sensor can be readily adapted as a ball IC using the fabrication techniques described in Applicant's U.S. Patent Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of K^+ concentration in a fluid is processed in accordance with the circuitry shown in FIGURE 3 as described above to produce a signal for transmission by ball IC to a remote station for outside monitoring. Alternatively, a sensor fabricated in accordance with the teachings of FIGURES 5a, 5b and 6 but with the gate oxide layer used there replaced with a gate oxide layer formed from K^+ sensitive material can be used to measure the concentration of K^+.

In an illustrative embodiment, there is shown in FIGURE 5c a portion of an artery 500 in which a catheter 505 having attached thereto a ball semiconductor IC 510 configured with a sensor 560 for sensing the presence in the bloodstream 512 of positive ions designated collectively by the reference numeral 515. It will be appreciated that the ball 510 and its sensor 560 are in contact with the biological medium being sensed, i.e., the bloodstream 512 and the positive ions 515, representing in this illustrative example, sodium Na^+ ions. The signal from sensor 560 is coupled to processor 540 where an electrical signal representing the sensed ion concentration is generated. The electrical signal thereby generated is then coupled to RF transmitter 50 to modulate an RF carrier, which modulated carrier is coupled to power coil 520 to be radiated to an external monitor device. FIGURE 5c thus illustrates one typical mode of operation of the ball semiconductor IC of the present disclosure configured with a sensor for obtaining information about the biological medium with which it is in contact and processing that information for wireless transmission to an external device where it may be received and processed for observation and review.

Conventional Na^+ and Cl^- sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw-Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995), which are incorporated herein by reference. Fabrication of these kind of sensors can be readily adapted to a ball IC using the fabrication techniques described in Applicant's U.S. Patent Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by sensors so fabricated and indicative of Na^+ or Cl^- concentrations in a fluid are processed in accordance with the circuitry shown in FIGURE 3 as described above to produce a signal for transmission by spherical IC to remote station 140 (shown in FIGURE 2) for outside monitoring.

As a result of the interfacial potential of the fluid-insulator interface produced by the net surface change due to the ionization and complexation with K^+ or Na^+ ions in the blood, the channel conductance of the ISFET is affected in the same way as the external gate voltage applied to the reference electrode.

As described above, the semiconductor ball IC can be introduced either attached to a guidewire, stylet, catheter, needle, trocar, fiberoptic device or alone into blood vessels, peritoneal or thoracic cavities, sinuses, joint cavities, ocular, otic, gastrointestinal, respiratory, urogenital,

and reproductive systems, intraventricular, epidural, subarachnoid, intracerebral, intramuscular, and in extracellular fluid compartments for determining K^+, N^+, Cl^- or other ion concentrations especially during surgical procedures where monitoring of these values may be critical.

In another embodiment, a semiconductor ball attached to a guidewire, stylet, catheter, needle, trocar, fiberoptic device or introduced alone may be adapted for measuring the partial pressures of oxygen pO_2 and carbon dioxide pCO_2 in blood vessels, peritoneal or thoracic cavities, sinuses, joint cavities, ocular, otic, gastrointestinal, respiratory, urogenital, and reproductive systems, intraventricular, epidural, subarachnoid, intracerebral, intramuscular, and in extracellular fluid compartments.

Conventional pO_2 and pCO_2 sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of these kinds of pO_2 and pCO_2 sensors can be readily adapted to a ball IC using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by sensors so fabricated and indicative of O_2 and CO_2 gas concentrations respectively are processed in accordance with the circuitry shown in FIGURE 3 as described above to produce a signal for transmission by ball IC to a remote station for outside monitoring.

In another embodiment, a semiconductor ball attached to a guidewire, stylet, catheter, needle, trocar, fiberoptic device or introduced alone has been adapted for measuring selective carbohydrates in blood vessels, peritoneal or thoracic cavities, sinuses, joint cavities, ocular, otic, gastrointestinal, respiratory, urogenital, and reproductive systems, intraventricular, epidural, subarachnoid, intracerebral, intramuscular, and in extracellular fluid compartments.

Conventional glucose sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). These sensors frequently rely on the oxidation of glucose under

the action of glucose oxidase or other oxidizing agent, with readout of the shift in oxygen partial pressure or pH. Fabrication of this kind of a sensor can be readily adapted to a ball IC using the fabrication techniques described in Applicant's U.S. Patent Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of glucose concentration in a fluid is processed in accordance with the circuitry shown in FIGURE 3 as described above to produce a signal for a remote station or outside monitoring.

Conventional carbohydrate sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a sensor can be readily adapted to a ball IC using the fabrication techniques described in Applicant's U.S. Patent Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of carbohydrate concentration in a fluid is processed in accordance with the circuitry shown in FIGURE 3 as described above to produce a signal for a remote station or outside monitoring. In a similar manner, the semiconductor ball can be adapted in other embodiments for measuring proteins, lipids, phospholipids, enzymes, cell integrins, hemoglobin, neurotransmitters, or other physiologic chemical parameters.

Referring now to FIGURE 6, there is illustrated yet another embodiment, a ball semiconductor IC 40 that is adapted to utilize pressure transduction properties. Fabrication of such an IC is disclosed in Applicant's U.S. Provisional Patent Application Serial No. 60/110,106 entitled *INTRALUMINAL MONITORING SYSTEM* filed November 25, 1998 and is incorporated herein by reference. FIGURE 6 in the present disclosure illustrates two embodiments. In one embodiment, a ball semiconductor IC 640 having a pressure sensor is adapted to catheter 650 and inserted into the cranial cavity 622 or intraventricular space to monitor cerebrospinal fluid (CSF) pressure as shown in FIGURE 6. In another embodiment, a ball IC 630 having a pressure sensor is implanted into subarachnoid space 630 to monitor pressure build-up in this region of the subarachnoid space 632.

The ball semiconductor IC 640 may be attached to a guidewire, stylet, catheter, needle, trocar or fiberoptic device or introduced alone to monitor pressure in blood vessels, peritoneal or thoracic cavities, sinuses, joint and extracellular spaces, ocular, otic, gastrointestinal, respiratory, urogenital, and reproductive systems. Further, cerebral-spinal fluid (CSF) pressure may be monitored in intraventricular, epidural, subarachnoid, and intracerebral locations. In certain locations such as intracerebral (including subarachnoid or intraventricular locations), epidural locations, and Intraocular locations disorders can arise leading to increased tissue or fluid pressure requiring frequent monitoring to alleviate pressure build-up and tissue destruction. The present embodiment can detect this condition and allow for appropriate measures to be taken to correct the elevated pressure.

In still another embodiment, acoustic, radar, and optical sensors are adapted to the ball semiconductor IC of the present disclosure to determine the flow of fluid. Some sensors of this type are disclosed in Applicant's U.S. Provisional Patent Application Serial No. 60/110,106 entitled *INTRALUMINAL MONITORING SYSTEM* filed November 25, 1998 and is incorporated herein by reference.

Conventional acoustics, radar and optical sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of these kinds of sensors can be readily adapted as a ball IC using the fabrication techniques described in Applicant's U.S. Patent Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of flow rate of a fluid is processed in accordance with the circuitry shown in FIGURE 1 as described above to produce a signal for transmission by ball IC to a remote station for outside monitoring.

Conventional position sensors are also known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a sensor can be readily adapted as a ball IC using the fabrication techniques described in Applicant's U.S. Patent Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of position is processed in accordance with the circuitry shown in

FIGURE 1 as described above to produce a signal for transmission by ball to a remote station (See FIGURE 2) for outside monitoring.

FIGURE 7 shows a cross-section 720 of a trachea of a subject. In this embodiment, one or more of balls 731, 732, 733, 734 with position or vibration transduction properties can be attached with tissue glue to vocal cords 722, 724 to sense their movement. One position sensor of the kind disclosed in Applicant's U.S. Provisional Patent Application Serial No. 60/110,106 entitled *INTRALUMINAL MONITORING SYSTEM* filed November 25, 1998 may be used here, with the circuitry disclosed there for conversion to radio frequency.

In another embodiment, a position sensor may be attached or integral with fingertips of Latex gloves to determine distance between two fingers when a physician is unable to visualize that distance, for example in a vaginal examination to determine the distance between the pelvic bones to assess adequacy of the birth canal during pregnancy. The position sensor may also be directly attached to the cervical os to determine cervical dilatation during labor without the discomfort or risk of infection of repeated digital examinations. Still further, the position sensor may also be located on scalpel blades or scissors to determine, during pelvic or abdominal surgery, the distance of the blades or scissors from a catheterized ureter also containing position sensors. The position sensor balls may also be used to detect movement (or displacement) and can be positioned over several ribs or intercostal muscles to detect respiratory movements. Alternatively, position sensors can be temporarily affixed to bone along the outer lip of the trochanteric fossa allowing an orthopedic surgeon to correctly align the position of an artificial hip, containing additional position sensors, to achieve the proper hip joint angle of inclination. Improper alignment of the hip joint which is currently determined by manual and visual means is a major morbidity associated with artificial hip replacement. Thus, the position sensor-containing ball semiconductor IC can provide position location information of two moving internal or external body parts through radio frequency communication to an outside central processing unit. Likewise, the relative positions of an inanimate object (such as suture or scalpel) and an internal vital structure containing a similar position sensing ball may also be determined and indicated.

In another embodiment, body temperature is measured using a ball semiconductor sensor IC of the present disclosure. The temperature sensor ball may be placed on a catheter, needle, stylet, guidewire, into blood vessels or ingested or placed into the gastrointestinal tract alone or by catheter for continuous monitoring. The temperature ball may likewise be placed externally adjacent to the tympanic membrane for monitoring of the temperature. A disclosure of a temperature sensor attached to the semiconductor ball and the circuitry involved in the conversion to radio frequency appears in Applicant's copending U.S. Provisional Patent Application Serial No. 60/110,041 filed November 25, 1998 entitled INTERNAL THERMOMETER filed contemporaneously with the filing of this application and incorporated herein by reference.

Bioelectric signals are associated with almost every organ system in the body. These signals may be continuous or intermittent and either low or high in their signal intensity. Several of these signals are of vital importance and represent the normal functioning of the brain, heart, muscles, and nerves of the body. Surface bioelectrodes can be used to monitor electrical activity of the heart. Cardiac arrhythmias, conduction system disease, and diagnosis of myocardial ischemia/infarction, myocarditis, and pericarditis can be ascertained by electrocardiographic activity monitoring of the heart. For an illustrative example, see Applicant's co-pending U.S. Patent Application, Serial No. 09/323,585, entitled *IMPLANTABLE EPICARDIAL ELECTRODE* filed May 28, 1999 and incorporated herein by reference.

Conventional surface electrodes are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of an electrode can be readily adapted as a ball electrode using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of electrical activity are processed in accordance with the circuitry shown in FIGURE 1 as described above to produce a signal for transmission by the ball IC to a remote station for outside monitoring.

The electrode can also be positioned for monitoring electrocardiographic activity. In addition to conventional skin surface and catheter tip electrodes, in certain instances, the ball semiconductor may be attached to the cardiac muscle surface directly with tissue glue for monitoring during cardiac surgery or electrophysiologic (epicardial electrodes, for example) testing.

Similarly, in yet another embodiment, a ball can be attached to the scalp or implanted into the subarachnoid space or directly onto the cortical surface to monitor electroencephalographic (EEG) activity. Monitoring of EEG activity can be used to determine seizure activity and location as well as the presence of underlying cerebral dysfunction. The EEG is also an essential component for monitoring in sleep studies. On detection of physiological conditions inductive of the onset of a seizure activity, appropriate measures can be taken to alleviate the seizure and to otherwise provide for the safety of the patient.

A bioelectric sensor according to the present disclosure may also be used to detect electrical activity at other points of the body. A ball can be externally attached to a surface of a patient's skin or inserted as part of a microelectrode or even implanted to serve as a monitor of muscle activity (electromyographic monitoring) or nerve activity (nerve conduction velocity) for the diagnosis and evaluation of neuromuscular disorders. Electrical activity of lesser intensity is generated from many other organ systems and may be monitored to determine organ function, for example gastrointestinal motility can be monitored by placement of ball semiconductor attached with tissue glue to the esophagus, stomach, small and large intestines.

For orthopedic applications, the ball sensor, either a single ball or a plurality thereof may be inserted into a bone, tendon or ligament for assessing stress or compression forces. This may be particularly beneficial in monitoring the stress or compression force generated on vertebral discs in individuals required to lift heavy objects as well as post-menopausal women who frequently develop vertebral compression fractures secondary to osteoporosis. Likewise, the ball IC may be useful for monitoring bone or external fixation device stresses during the various stages of compression and tension in Ilizarov procedures, and employed similarly for general range of motion of orthopaedic internal

and external fixation devices. In addition, ball semiconductors containing sensors to assess stress forces can be attached to artificial joints during experimental development in order to construct a joint with improved joint stability and longevity. Communication between ball ICs would be via RF as well as communicating with a CPU where transmitted information can be assessed and analyzed.

FIGURE 8 shows an array of several ball semiconductor ICs 732-737 used to assess stress or compression forces between an artificial hip 720 and normal bone 740. A stress sensor located on a ball attached to normal bone near the insertion site of an artificial hip joint as shown to monitor for instability and proper hip function or to monitor the onset of degenerative processes which might subsequently require a revision of surgical procedure. Early warning of such prosthetic device instability is desirable in order to minimize the magnitude of the revision procedure, enhance proper healing and limit patient morbidity.

Conventional stress sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a sensor can be readily adapted as a ball using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of stress is processed in accordance with the circuitry shown in FIGURE 1 as described above to produce a signal for transmission by ball to a remote station (See FIGURE 2) for outside monitoring.

In another embodiment, the ball semiconductor may contain a radiation sensor. FIGURE 9 shows a tumor 910 with a radiation sensor ball 920 placed inside the tumor by needle insertion or surgical placement. Sensor ball 920 detects radiation from an external source and can be used to determine accurate dosiometry. An array of radiation sensor balls 930-944 placed at the periphery of the target field of radiation may be used to monitor radiation dosiometry to normal tissues from external radiation.

Conventional radiation sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of sensor can be readily adapted to a ball IC using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of radiation is processed in accordance with the circuitry shown in FIGURE 1 as described above to produce a signal for transmission by a ball to a remote station for outside monitoring.

In another embodiment, fluid viscosity is determined by a viscosity sensor located in joint spaces to monitor inflammatory arthritic conditions of the joints.

Conventional viscosity sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a sensor can be readily adapted as a ball using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of viscosity is processed in accordance with the circuitry shown in FIGURE 1 as described above to produce a signal for transmission by the ball sensor to a remote station for outside monitoring.

The sensor may be implanted within the cartilage surface or along a ligament which is a portion of the joint capsule. As is true of certain implantable sensors they will be coated with biocompatible materials such as iridium oxide on top of a thin titanium layer as is used to coat long term indwelling accelerometer sensors in implantable pacemakers.

In further embodiments, a ball semiconductor is provided with multiple sensors to measure several physiological conditions at a single site on one ball or multiple balls can be clustered together with one or more sensors per ball. In an illustrative embodiment, an enlarged view of a three-ball monitor 1080 is shown in FIGURE 10. In this figure, one or

more sensors can be adapted to one, two or all three of the balls shown. Connections between the balls are made through metal contacts. FIGURE 11 illustrates a section taken through the junction of four contacts 1188-1187 between ball 1182 and ball 1183. The contacts 1184 and 1185 may be power contacts, providing, for example, a positive 3.0 volts relative to ground, which can be passed from ball 1081 around ball 1082 by conductors on its surface using two of a group of similar contacts (designated collectively by numeral 1090 in FIGURE 10). The contacts 1186 and 1187 may be data and control contacts for communications between ball 1082 and ball 1083. Similar data and control contacts may exist among contact group 1090 between ball 1081 and ball 1082 to the extent needed.

Now referring to FIGURE 12, a cluster of balls 1291, 1292, 1293, 1294, 1295 and 1296 is shown as an example of the versatility of such ball systems. The cluster specifically shows six balls arranged in a three-dimensional configuration. It will be appreciated that various other cluster arrangements are possible, limited only by the constraints of the end-use application. Each of the balls of the cluster can perform different electronic functions and communicate with each other through contacts as described above in connection with FIGURES 8 and 9.

Powering of the IC balls can be implemented in accordance with the teachings in Applicant's U.S. Provisional Patent Application Serial No. 60/110,106 filed November 25, 1998 entitled *INTRALUMINAL MONITORING SYSTEM* and U.S. Provisional Patent Application Serial No. 60/110,041 entitled *INTERNAL THERMOMETER* filed November 25, 1998 and incorporated herein by reference.

Several techniques can be used to place a ball semiconductor IC at the site targeted. For intravascular applications, the ball semiconductor IC can be injected or implanted alone as a unit or attached by catheter, guidewire, stylet or needle. For intracerebral applications, such as the subarachnoid, intraventricular, or epidural spaces and intracerebral or spinal cord locations, the ball can be injected or implanted as a unit or alone or attached to a catheter, guidewire, stylet, trocar or fiberoptic device or needle. For pulmonary applications, the ball can be inhaled or inserted attached to a catheter, guidewire, stylet or bronchoscope. For gastrointestinal applications, the spherical-shaped

IC can be ingested, implanted or attached to a catheter or endoscope. For kidney applications, the semiconductor ball IC can be implanted, inserted, or attached to a catheter for angioplasty procedures, guidewire, needle, stylet, trocar or fiberoptic device or placed on a stent that can be located in the renal pelvis, ureter, bladder, urethra, prostate or other area of the kidney.

The fabrication of a spherical-shaped ball semiconductor IC for use with a stent is disclosed in Applicant's U.S. Provisional Patent Application Serial Number 60/110,106 entitled *INTRALUMINAL MONITORING SYSTEM* filed November 25, 1998 and is incorporated herein by reference. While the application of the ball semiconductor IC with stent structure disclosed therein is primarily for use in monitoring pressure and flow within a luminal structure, it will be appreciated that any biochemical measurement such as pH, K+, glucose or protein as illustrative examples may be monitored by the stent- adapted ball semiconductor IC as described above. As one particular example, a ball semiconductor IC configured as a pH sensor may be associated with a stent located along the urethra for purposes of monitoring pH levels in a urine stream.

For circulatory assist device applications, the ball can be placed singly, or serially within the inlet, outlet, or pumping chambers of ventricular assist devices, or artificial hearts. The primary application in this instance is for use in monitoring and controlling pressure and flow within the structure, thus regulating the total systemic and/or pulmonary blood flow.

For female reproduction applications, the ball semiconductor IC sensor may be inserted, implanted or attached by catheter, guidewire, stylet, needle, or implanted by digital insertion. Such an IC can be located within the uterus, fallopian tubes, ovaries, cervix, or vagina, for example, to detect pH as a change may occur with placental sac rupture, to monitor pressure during uterine contractions, or to monitor fetal heart rate during pregnancy.

Some of the many uses of the ball of this invention and several ways these spherical, ovoid, and ellipsoid-shaped ICs, sensors, actuators, clinometers, accelerometers

and gyroscopes can be adapted for use in the body arc shown in Table I of this Application.

TABLE I

Implant	Location	Task
Inserted via, or placed on catheter, endoscope, laparoscopic device, (including attachment to surface)	Artery, vein or capillary	Measures pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, pressure, flow, velocity, force (shear, compression), viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell integrins, and other cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, guidewire, endoscope, laparoscopic device, including attachment to surface	Intracerebral (subarachnoid space, intraventricular, spinal cord, epidural space	Measures pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, pressure, force, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell integrins, and other cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted or on catheter or needle	Intraocular (lens, choroid, sclera)	Measures pH, temperature, pO2, PCO2, pressure, force, proteins, lipids, phospholipids, enzymes, cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Intraacoustic (outer, middle, inner ear)	Measures temperature, pO2, PCO2, pressure, force, proteins, lipids, phospholipids, enzymes, neurotransmitters, cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Sinus Cavities	Measures pH, ions (Na+, K+, Cl-), temperature, pressure, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Pulmonary (airway and its branches at all levels, vasculature and its branches at all levels, parenchyma)	Measures pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, pressure, flow, velocity, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell integrins, and other cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Gastrointestinal	Measures pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, pressure, flow, velocity, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell integrins, and other cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Kidney and urinary tract (renal blood vessels, tubular apparatus, pelvis, ureter, bladder, urethra)	Measures pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, pressure, flow, velocity, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell integrins, and other cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Female reproductive organs (in or on uterus, fallopian tubes, ovaries, cervix, vagina)	Measures pH, ions (Na+, K+, Cl-), temperature, pressure, flow, velocity, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, lipids, phospholipids, enzymes, cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Bones, joints and adjacent cartilage and extracellular matrix (in or on)	Measures pH, ions (Na+, K+, Cl-), temperature, pressure, flow, velocity, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, lipids, phospholipids, enzymes, cell integrins and other cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Biliary tract	Measures pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, pressure, flow, velocity, force (shear, compression), viscosity, sugars, carbohydrates, proteins, lipids, phospholipids, enzymes, cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position

Implant	Location	Task
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Intra-abdominal cavity	Measures pH, ions (Na+, K+, Cl-), temperature, pressure, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	CSF (intraventricular, epidural, subarachnoid spaces, or intracerebral)	Measures pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, pressure, flow, velocity, force, (shear, compression), viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Inserted via, or placed on catheter, endoscope, laparoscopic device, including attachment to surface	Brain surface	Measures electrical activity Measures pH, ions (Na+, K+, Cl-), temperature, pressure, force, (shear, compression), carbohydrates, proteins, lipids, phospholipids, enzymes, neurotransmitters, cell membrane receptors, electrical potential, radiation, acoustics, optical CCD, and position
Implantable position or vibration sensor	scissors, needles, scalpels, endoscopes or laparoscopic devices outside the body	Senses vocal cord movement, rib cage movement, instrument and vital structure location
Implantable	Intraocular, intracerebral Sinus cavity	Monitors pressure
Implantable EEG sensing device with ability to deliver drugs from a reservoir via pump or diffusion actuator, or deliver electrical waveform via actuator	Brain, phrenic nerve	Allows detection of seizure activity and releases anti-seizure medication or effects electrical stimulation to treat seizure locally without systemic side-effects
Implantable within or on surface of intracorporeal or extracorporeal circulatory assist device	Left ventricular assist device, right ventricular assist device, total artificial heart, intraaortic balloon pump	Monitors and controls device pressure, flow, velocity, acceleration and or vibration, thus regulating the cardiac output and/or total systemic and pulmonary blood flow.
Implantable within the mechanism, or on surface of intracorporeal or extracorporeal heat or mass exchanger	Blood heat exchanger, blood oxygenator, hemodialyzer, plasmapheresis device, filtration device, cell separation device	Monitors and controls device pressure, flow, velocity, acceleration, vibration, pH, ions (Na+, K+, Cl-), temperature, pO2, pCO2, viscosity, sugars, carbohydrates, proteins, hemoglobin, lipids, phospholipids, enzymes, neurotransmitters, cell integrins, and other cell membrane receptors, electrical potential, thus regulating the flow, temperature, fluid composition, mass transfer or filtration rate of the assist device.

3. Diagnostics and Imaging Applications

The main function of diagnostic imaging is to produce images of internal organs of the body for diagnostic purposes. In one technique, x-rays are used to produce shadow images of internal organs of the body. Computer tomography is another x-ray based technique where a narrow x-ray beam is passed through a body at several points along a plane so as to produce an image with some 3-D perception. Ultrasound is yet another imaging system used for diagnoses. The principles of nuclear magnetic resonance are also

utilized in devices used for imaging. Nuclear medicine involves injection of a radio-labeled substance that is selectively distributed to specific areas of the body. Magnetic resonance imaging is a recent development in imaging and allows for 3-D perception as well as determining organ function under certain conditions. Conventional imaging radiology is based on these and other imaging techniques.

In a preferred embodiment, magnetic resonance imaging can locate a semiconductor ball without the use of harmful x-rays. This would be very beneficial when located on a catheter for visualization and location for intricate manipulations in the intravascular space or inside the cranial cavity or any other body location. In addition, no contrast is needed for this visualization, thus decreasing the incidence of allergic reactions and contrast-induced nephrotoxicity. In another embodiment, the use of Doppler imaging via an acoustic emitter and acoustic receptor present on different semiconductor balls on the same guidewire or catheter would allow for intravascular imaging of the vessel. The acoustic emitter could also transmit a signal to an external acoustic receiver to allow for imaging of vessel wall thickness and perivascular structures.

In another diagnostic embodiment, the semiconductor ball of the present disclosure lends itself readily to 3-D pressure monitoring because of the spherical surface of the ball which allows each sensor to be positioned away from the other so as to be displaced from the other in all three axes. For example, a sensor located at the top of ball 10 and a second sensor located at a midpoint along the surface of the ball could be displaced and/or oriented from each other in all three x, y and z axes. This is unlike conventional flat surface ICs where sensors are displaced from each other in only the two dimensions - for example, the x and y axes.

In still another application, a ball is adapted with a charge-coupled device (CCD) or digital signal processor having optical sensory properties placed at the end of an endoscope, arthroscope, bronchoscope, vasculoscope or laparoscope providing for 3-D panoramic images without requiring movement of the end of the scope as opposed to the conventional limited planar views obtained with the current flat chip which require movement of the end of the scope for visualization in other planes of view. The appearance may be similar to that viewed through the eye of a fish. As this is on the end

of an endoscope it allows for a decrease in the endoscope caliber making more sites accessible. The connection to the outside central processing unit may be direct through wire connections inside the endoscope or wireless via radio frequency conversion. The latter would allow for a further decrease in caliber of the endoscope.

Turning now to FIGURE 34, it is shown that, alternatively, ball ICs can be arranged onto flat panel x-ray detectors where they are capable of digitally x-ray imaging a portion of the human body by converting incident x-rays directly into electric charges and obtaining electrical signals therefrom. These flat panel x-ray detectors remove the need for film emulsions and the requirements for processing and developing photographic film. These flat panel x-ray detectors allow radiographic images to be created on view screens. The clarity of the image is determined by the resolution of the image that is defined by the capacity to show details separated in the x-ray image if they are separated in the viewed object. In the preferred embodiment, each ball sensor arrayed in a panel relays evidence for energy detection to a CPU. The sensor on each ball encompasses only a small area and can send information signaling excitation only for that specific area. Shown in FIGURE 34 is a sectional view of the upper surface of a flat plate detector demonstrating multiple layers of ball ICs 10 arrayed on a substrate 250 to maximize resolution of the viewed image. Upon each spherical IC are a plurality of x-ray detection pixels utilizing a Schottky diode configuration to convert the detected x-ray into an electrical signal. This arrangement can increase the sensitivity for detection of x-rays and thus lead to enhanced resolution.

Some imaging applications of the spherical-shaped semiconductor ICs are summarized in Table 2.

TABLE 2

Implant	**Location**	**Task**
On catheter or end of an endoscope	Any body cavity	CCD, Digital signal processing unit for panoramic 3-D view of objects or surfaces
Catheter	Any location listed above	Gives location of the catheter without the use of x-rays

4. Electronic Patient Monitoring Applications

Patient monitoring is concerned with the continuous observation of seriously ill patients, including observation, physical examination, recording of physiologic variables, and intervention and administration of therapy when necessary. Conventional electronic devices are used to monitor, display, record and make elementary decisions concerning a patient's condition.

As described in the Diagnostics section hereinabove, electrocardiographic monitoring is usually performed by placing surface bioelectric electrodes on the patient's chest wall. Permanent indwelling pacemakers have an accelerometer that coordinates atrial and ventricular contractions. The ball may also have an accelerometer sensor that would allow it to be a portion of the electrode required for pacemakers currently in use or allow it to communicate wirelessly via radio frequency to a subcutaneously placed CPU which in turn could send a signal to a second ball sensor which elicits an electrical discharge along an atrial or ventricular portion of the cardiac conduction system.

In a Coronary Care Unit, for example, an abnormal arrhythmia condition in a patient in whose body is implanted a ball sensor IC may provide a signal which is transmitted to a host device which elicits an alarm. FIGURE 13 shows the use of a ball IC in such a system. Receiver circuitry 1360 comprises a receiver 1361, processor 1362, data display 1363, data recorder 1364 and alarm 1365. When an abnormal rhythm such as ventricular tachycardia or fibrillation occurs the signal is detected by receiver 1361, and

appropriately processed for display on data display 1363, recording on data recorder 1364 and activating an alarm 1365. Data display 1363 can be a long-persistence phosphor display or a display with a continuously updated memory. Data recorder 1364 can be a recording oscillograph or other device for providing a permanent record. Alarm 1365 is an alarm circuit that sets off an alarm when the heart rate exceeds a maximum or falls below a minimum as determined by the processor. Preferably, processor 1362 uses the information generated by a ball 1350 configured as a sensor to calculate heart rate by averaging the beat-to-beat period measurement. This invention is displayed on data display 1363 and can be recorded permanently using data recorder 1364. If the heart rate falls outside of acceptable ranges programmed into the processor, the heart alarm circuit 1365 sets off an alarm. In another embodiment, alarm 1365 may be connected to data recorder 1364 to automatically record the event that set off the alarm. The ball IC electrodes may be located on the skin surface, implanted subcutaneously or implanted directly on the epicardial surface.

In still another embodiment, a ball with appropriate sensing elements may be located at a variety of critical sites through the body. For instance, in addition to heart rate, other physiological variables such as pH, oxygen and carbon dioxide levels may be monitored by ball sensors located in the blood vessels or a lung.

Besides coronary-care applications, patients with other acute illnesses, in shock, or suffering from severe burns, as well as those undergoing and recovering from surgery often require intensive monitoring. In these patients, several vital signs must be monitored continuously. In addition to heart rate and ECG, ball sensors can be used to measure arterial pressure, peripheral blood pressure, peripheral and core temperature, respiratory rates, tissue and blood stream oxygenation, blood gases, or cerebral electrical activity. Blood pressure can be measured by cannulation of an artery with a ball that contains pressure transduction properties. Fabrication of such an IC has been disclosed above. Similarly, blood pressure can be measured by placement of a surface pressure transducer located on the arm or leg overlying an artery with a ball that exhibits pressure transduction properties.

Temperature in the gastrointestinal tract and upon the skin at various locations can be monitored by a ball with a temperature sensor. A ball sensor for temperature is disclosed in Applicant's U.S. Provisional Patent Application Serial No. 60/110,041 entitled *INTERNAL THERMOMETER* filed November 25, 1998 and is incorporated herein by reference.

Blood gases may also be monitored using the ball sensor of the present disclosure. The partial pressure of oxygen and carbon dioxide in the circulating blood can be monitored by balls using invasive or noninvasive techniques. With invasive techniques, the ball is introduced into the bloodstream on a catheter, needle, stylet or injected alone into a peripheral non-vital capillary. With noninvasive techniques, a ball can be located on opposite surfaces of a digit or ear lobe to assess oxygen saturation of hemoglobin or reflective oximetry. In this embodiment, a ball adapted to exhibit optical transduction properties monitors color changes in the blood.

Conventional optometer sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a sensor can be readily adapted as a spherical IC using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of light is processed in accordance with the circuitry shown in FIGURE 1 as described to produce a signal for transmission by the ball to a remote station for outside monitoring.

In addition to intensive-care, operating room, and recovery room monitoring, the invasive system using balls can be applied to perinatal intensive care and ambulatory-patient monitoring. Intensive monitoring of mother, fetus and newborn in the period surrounding birth to detect and manage traumatic labors in high-risk pregnancies and premature or severely ill newborns may be performed as described above in the Diagnostics section. Fetal heart rate and uterine contractions during labor can be monitored using the invasive balls. In one embodiment, a ball is attached to the maternal abdomen. Alternatively, balls can be introduced into the uterine cavity during labor for

on-site readings of fetal heart rate. Uterine contractions can be detected by a ball attached to the abdomen. Preferably, a ball exhibiting strain gage transduction properties is used.

Conventional strain gauge sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a strain gauge can be readily adapted as a ball using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. Signals generated by a sensor so fabricated and indicative of strain is processed in accordance with the circuitry shown in FIGURE 1 as described above, to produce a signal for transmission by the ball to a remote station 140 (see FIGURE 2) for outside monitoring. Expansion and contraction of the abdominal wall is detected by the ball and can be directly related to uterine contractions.

For example, balls of this invention can be placed into the uterine cavity for obstetrical monitoring. The balls can be placed there either transabdominally or through the vagina when labor has progressed far enough to allow rupture of fetal membranes. Direct uterine pressure recordings can be made by placing a ball of this invention into the uterine cavity. Further, monitoring of premature, postoperative, and seriously ill newborns can be made using methods involving balls in a similar way to their use in adult intensive care.

In still another application, the spherical-shaped ball semiconductor IC of the present disclosure further allows for electronic monitoring of an ambulatory patient. Ambulatory electrocardiographic and electroencephalographic monitoring can be performed continuously without the need for cumbersome wires. The external CPU may typically be a recording device with memory worn on a belt similar to a beeper or telephone. Radio frequency communication is used to transmit the signal from the surface electrodes to the CPU. A spherical-shaped IC with appropriate sensors can be optimally located to measure the physiological variable of interest. Randomly occurring events such as cardiac arrhythmias can be detected with an appropriately configured spherical-shaped IC according to the present disclosure.

5. Stimulation, Therapy and Treatment Applications

In another class of applications, the ball semiconductor may be configured as an actuator to stimulate excitable tissue. The semiconductor ball can function as a Transcutaneous Electrical Nerve Stimulator (TENS) unit. This is very important in treating chronic pain syndromes. The TENS unit can also be used to stimulate both nerve and muscles in paralyzed or injured limbs to help prevent the development of atrophy or as a means to reduce the inflammatory response. Multiple balls which function as both receivers of electrical signal and also as transmitters of signal could function as a bridge between the intact portion of an amputated limb and a moveable prosthetic hand or foot, for example, attached thereto.

In another embodiment, it is envisioned that a ball containing CCD or digital signal processing and optical sensing capabilities may be connected to a retina or individual optic nerve fibers to stimulate adjacent nerve fibers to give depth and width to the image and increase visual acuity in sight impaired individuals. Surface acoustic wave piezoelectric sensors have recently been used as odor detectors. Using either surface acoustic wave or metal-oxide-silicon field-effect transistors on multiple balls permits creation of an electronic nose to detect odors. In another embodiment, spherical-shaped IC's are located along a malleable metal rod that may be inserted into the cochlea as is currently done for cochlear implants. Currently, the metal does not always remain in direct contact with the vestibulocochlear nerve, thus creating a decreased ability of the ear to distinguish between sounds. The present embodiment allows for multiple balls to be centered on the malleable rod and sense endolymph fluid wave motion (acoustic sensor) and transduce this into an electrical stimuli for vestibulocochlear nerve stimulation. The ability to place multiple balls on the same malleable rod allows for increased sound discrimination. This device uses an intact tympanic membrane to stimulate an endolymph wave and thus functions as a hearing aid. Alternatively, multiple acoustic sensing balls can be placed at or near a damaged tympanic membrane to serve as acoustic sensors and acoustic transmitters.

In yet another embodiment, a ball of the disclosed embodiment is adapted to exhibit heat emitting properties when contacted by radio frequency energy. Conventional

heat sensors are known in the art. See, for example, *ELECTRONIC ENGINEER'S HANDBOOK*, 2nd Edition, Fink Christianson, McGraw Hill (1982); and *BIOMEDICAL ENGINEERING HANDBOOK*, Joseph D. Bronzino, Editor-in-Chief, CRC Press (1995). Fabrication of this kind of a sensor can be readily adapted as a ball IC using the fabrication techniques described in Applicant's U.S. Patent Application Number 5,955,776, issued September 21, 1999 referenced above. As an illustrative example, the semiconductor ball of the present disclosure can be placed into a tumor region to deliver tissue destructing heat waves. Multiple other balls may be placed around the tumor to function as heat sensors to monitor the heat produced to keep the heat generating ball from destroying normal tissue. The semiconductor balls can also selectively deliver destructive ultrasound, laser ablative energy or radiation energy to the tumor and monitored by multiple balls placed around the tumor to regulate tissue injury and destruction. Semiconductor balls serving as acoustic transmitters can also function as sonicators turning semi-solid material into liquid material. This is especially helpful in patients suffering from sinusitis.

Table 3 summarized some ways spherical, ovoid or ellipsoid ICs, biosensors and actuators of the present disclosure may be adapted to the body.

TABLE 3

Implant	**Location**	**Task**
Actuator (implantable or external)	Skin surface or implantable on muscle surface	TENS unit (nerve stimulation for relief of pain)
Implantable sonicator	Sinus	Sonicator to loosen up and liquefy thick mucous
Implantable nerve stimulator/muscle stimulator	Nerves and muscles paralyzed in accidents, or immobilized for long periods while healing	Prevents disuse atrophy

Infrared/laser/ultrasound	Malignancies	Delivery of infrared, laser, or sonogram to ablate tumors with sensors to detect the perimetery of the tumor and where "normal" tissue begins

6. Prosthetic Devices and Artificial Organ Applications

Prosthetic devices are commonly used to replace a missing body part such as a limb, an eye or a heart valve. Artificial organs are often used to replace or function as different organs such as kidney, blood, pancreas and parts of a heart. Providing smart technology to prosthetics and artificial organs allow greater versatility in operation and/or monitoring of these parts and the body regions in which they are placed.

FIGURE 8 shows one embodiment of a prosthetic device, where an artificial femur replacement is provided with spherical-shaped IC located in the normal bony structure of the femur shaft. In this location, stress and compression forces can be monitored to assure proper alignment of the hip joint, minimizing stress on other joints such as the opposite hip and the knee joint located on the same side as the prosthesis. As another example, in the vertebral column, material may be placed in vertebral discs to allow for a semi-synthetic vertebral disc to be constructed. Presently, the semi-synthetic disc is monitored only retrospectively and visualized on x-ray. With the use of semiconductor ball IC sensors according to the present disclosure, stress and compression forces can be easily monitored when such balls are implanted in the semi-synthetic disc.

Prosthetic devices containing multiple ball ICs can detect the angle of movement of a prosthetic device. Following artificial knee and shoulder replacement, increasing ranges of movement are required to rehabilitate the joint. Ball ICs can be programmed to elicit a signal once the goal range of motion is achieved. Every few days the goal can be increased to facilitate the recovery period postoperatively. Alternatively, following artificial hip replacement, the range of motion of the hip joint should initially be limited to

enhance the long term function of the prosthetic joint. A warning signal will be elicited if the angle of motion is exceeded. Each week the limiting range of motion of the hip could be increased, again to facilitate the recovery period postoperatively.

Movement of prosthetic limbs is currently not well coordinated because of the size required of instruments used to control artificial limb function. Small spherical-shaped semiconductors will allow this instrumentation to control functional hand and finger movements. Similar features are also be envisioned to control lower extremity prosthetic limbs. Cochlear implants, artificial vision and artificial smell are discussed above. In yet another embodiment, the ball semiconductor may be used to control small minipumps or other delivery actuators for the controlled slow release of medications or hormones.

These prosthetic device applications of spherical, ovoid or ellipsoid-shaped ICs are summarized in Table 4.

TABLE 4

Implant	**Location**	**Task**
Implantable motion sensor/motion transmitter	Middle ear	Functions as a very small hearing aid device using an intact tympanic membrane and inner ear
Multiple balls on an implant	Cochlea	Multiple balls placed on an implant to function as a motion sensor in the endolymphatic fluid and create an electrical signal transmitted to the eight cranial nerve for hearing (Cochlear implant)

Implant	Location	Task
Inserted on a catheter or implanted	CSF (spinal fluid, intraventricular)	Pressure (or flow) monitoring. Increased intracranial pressure can be treated through regulation of a ball-valve monitor

7. Physiological Robotic Devices and Systems

A robotic device is defined as a machine element that operates automatically or by remote control. Balls according to the present disclosure may operate automatically or by remote control in the biomedical applications disclosed herein and thus may be classified as physiological robotic devices.

One illustrative physiological robotic device 1410 of this invention is shown in FIGURE 14. Robotics device 1410 there comprises a ball 1420 fabricated to exhibit one or more transduction properties. Processor 1490 here is analogous to processors previously described. Robotics device 1410 further comprises a controller 1400 operable to provide control signals to various motors, pumps, activators, switches, valves, reservoirs, plumbing and other mechanical and electrical devices via control lines 1401 through 1405, each of which may perform an action under the control of controller 1400 in response to signals generated by processor 1490. The spherical-shaped biomedical robotic IC permits greater mobility and access to body locations that are otherwise unreachable. Small fin-shaped actuators may be provided for steering and a rotor actuator may be provided for propulsion and movement.

In one application shown in FIGURE 15, a spherical-shaped IC 1510 is constructed with a pump 1540 that is connected on one end through plumbing 1530 to reservoir 1520 and on a second end through plumbing 1550 to a surface 1515 of the ball IC 1510. A medicine carried by spherical-shaped IC 1510 in reservoir 1520 to a treatment site can be released to the site through plumbing 1530 and 1550. The action of pump 1540 controlled by the controller 1400 of FIGURE 14 responsive to signals generated by processor 1490 as

shown in FIGURES 14 and 15. Initially, devices will be implanted to deliver medication locally to a site, but they can also be engineered to deliver systemically acting substances such as insulin in response to certain levels of detected substances such as glucose. Individually navigated ball ICs may also be constructed whose access to sites will be limited only by the size of the actuator fins required for propulsion through blood vessels. The spherical-shaped IC 1510 can also accommodate one or more actuator devices which release pharmaceuticals and/or bio-pharmaceuticals for gene therapy.

In the brain, a site of electrical discharge (seizure focus) may be approached via blood vessel access for applying a local discharge of anticpileptiform medicine to provide for seizure control without systemic side effects. Similarly, chemotherapy, heat, or radiation can also be delivered locally to tumors via blood vessel access without far reaching effects. Further, robotic ICs may also deliver local laser or rotary ablative therapy to blood vessels located throughout the body including sites in the cerebral circulation currently inaccessible. Locally delivered ultrasound emitters may provide for better demonstration of blood vessels anatomy when used in combination with a conventional external ultrasound acoustic receiver.

To better aid the IC in navigation and orientation within biological media or tissues, a tumor or bacterial antigen may direct the IC to the tumor or infection source through binding to specific antibodies anchored into the IC surface. Again, this would allow local delivery of treatment such as laser, ultrasound, heat, rotary ablation, and pharmacologic agents to tumors or bacterial foci.

Some examples of how the spherical, ovoid or ellipsoid ICs of the present disclosure may be used in physiological robotic systems are summarized in Table 5.

TABLE 5

Implant	Location	Task
Implant with antibody directed towards tumor antigens	Malignancies throughout the body	Locates tumors and can deliver treatment locally without the worry of systemic side-effects
Implant with antibody directed against bacterial antigens	Infections throughout the body	Localization of infections and delivery of treatment

In another embodiment, a ball IC containing gyroscopic capabilities, constructed as a ball within a shell and levitated with electrostatic forces, can serve both as a position sensor within the body as described earlier, or as a position sensor on an inanimate object such as a wheelchair to enhance directional movements and improve climbing capabilities.

8. Computerized Physiological Data Processing Applications

Diagnosis, medical record keeping, hospital information systems and community health-care facilities pose several operational problems involving pattern recognition, complex systems, human interaction, and economics. Many of these problems can be simplified by automation so as to allow these variables to be more easily monitored. The ball of this invention can greatly simplify these problems. In one example, the inventive ball may serve as a miniature information databank containing a person's biomedical history and vital statistics. Automated patient information allows comprehensive and reliable patient information to be immediately accessed as needed.

In one illustrative embodiment of such a miniature information databank, a spherical-shaped IC according to the present disclosure may be located in the gluteus maximus of a male patient. The IC is coded with patient medical information and/or vital statistics. Information such as an allergy of a patient to penicillin, a heart condition or other factor affecting treatment may be coded into spherical-shaped IC and retrieved from outside the body by interrogation from an external source. The source can be located in the admission or emergency room of a hospital, a doctor's office or other location. Alternatively, it can be portably carried in the ambulance, with a doctor or paramedic or other medical personnel. Such interrogation of the spherical-shaped IC with coded patient

history information allows immediate retrieval of patient history for use in diagnosis and treatment of a patient in emergency conditions. This information can also be valuable in non-emergency conditions since it can provide information about a patient which may not otherwise be available. For instance, when a patient is seeing a new doctor, the IC can provide a databook of health information which can be retrieved by a doctor on command. This allows for a quicker, more complete initial exam and results in a more informed diagnosis.

While forms currently in use by doctor offices and completed by a new patient provide the same information, such information is only as good as a person's recollection. In the preferred embodiment, the ball may be configured to provide an automated databank of this information which provides a complete, accurate record of this information independent of a patient's recollection.

In another embodiment, the ball of this invention may be coded with a person's vital statistics. Such statistics could include name, social security, address and phone number and who to contact in case of an emergency. Should a person become unconscious, as a result of an accident, for example, an interrogation of the ball could immediately provide information vital in identifying the person, and also who to contact as the next of kin. Such information is invaluable in determining what assistance an unconscious person may require. Should a person die in war, accident, natural causes or otherwise, such information allows for immediate identification of the person and means for notifying the next of kin. In addition, should a child become lost, for example, interrogation of an IC containing this kind of information provides information helpful in finding the parents of the lost child.

In any of these embodiments, privacy of the coded information is always a concern. The coded information may contain personal information intended for access only by persons such as doctors, paramedics or others who have been granted appropriate authorization. To protect the privacy of the coded information, the information retrieval system of the present disclosure will only allow for detection at very finite distances such as up to 5-10 cm. This will help maintain an individual's confidentiality. In addition, a spherical-shaped IC may also be coded with a unique device security ID. This ID would

serve as a "key" without which IC could not be unlocked by an interrogator. Consequently, only authorized personnel with the knowledge of ID would be able to unlock IC and initiate transmission of a data stream of information from the spherical-shaped IC. In this way, the process of information is produced since no data stream of information from the ball semiconductor IC can be initiated without first unlocking the transmission channel of IC using appropriate security information.

In still another embodiment, a ball located on surgical instruments sponges, any other medical product or device may be tagged and tracked during a surgical procedure. An interrogation of a patient by electromagnetic source can indicate presence or absence of any implement inside the body. This would help alleviate surgical errors and unnecessary surgery.

9. Other Invasive and Non-invasive Biomedical Applications

Recently, semiconductors have been proven to be useful for gene analysis. Semiconductors can be loaded with tens to hundreds of thousands of different oligonucleotide probes, each of which may have known sequences, lengths, and locations on the IC. In one illustrative embodiment of the present disclosure, a cylindrical column containing several hundred balls is constructed. Each ball may contain oligonucleotide probes and is designed to define a specific gene probe array. A blood sample is first run through a device that separates DNA double helixes into separate strands. The prepared blood sample is then applied to the top of the column and allowed to flow down the column. Multiple duplicate gene probe arrays may be devised to create increased sensitivity to the test. Because many gene probe arrays can be placed in the column a whole range of genes can be studied at once. Hybridization, which may occur between the prepared blood sample and the ball column, can be accomplished via a nonelectronic photolithographic technique using fluorescein labels or via an electronic method which forces hybridization through changes in electronic charge along the IC column. Multiple uses may be envisioned for the ball column, such as; identification of genetic disorders; quick (minutes rather than 24 to 48 hours) identification of bacterial or viral organisms and whether they contain the genetic machinery for developing resistance to specific antibiotic or antiviral agents.

In other biomedical applications, semiconductor ball ICs may be adapted for the purpose of clinical chemistry diagnosis. Antigens or antibodies can be adapted to the ball surface for detection of corresponding antigens or antibodies within the or outside the body. In one example, an IC adapted to detect DNA can be used in a clinical laboratory or research facility to detect DNA information in a material body.

It will be appreciated that other modifications of the above are possible without departing from the spirit and scope of the invention. For instance, in yet another embodiment of this invention a ball device is provided with two sensors. These sensors can monitor the same or different physiological activities. If the same physiological activity, such as pressure, is monitored, then ball 10 advantageously allows there to be two pressure readings to be taken for purposes of integrity or redundancy and/or 3-D pressure monitoring. Sensors for integrating variables or providing redundancy may be provided by locating two or more sensors located anywhere along the surface of the semiconductor ball in a high pressure area of the body where pressure differentials between the two are sensors are minimal. Alternatively, if the semiconductor ball is to be used in a low pressure area, the sensors should be located close together on the semiconductor ball so as to minimize pressure differentials between the two sensors.

If a different sensor is used, then a ball semiconductor advantageously allows two or more physiological parameters to be monitored by the ball. Because of the greater surface area of the ball when compared to conventional flat IC of similar dimensions, the ball advantageously allows for an increased number of sensors to be placed within the same space that would be defined by a conventional flat IC. Placement of the same type of sensors in the ball can allow for increased integrity, redundancy and 3-D monitoring of the physiological condition of interests. Placement of different sensors in the ball can allow for more comprehensive monitoring of a wider range of physiological parameters than allowed using conventional flat IC's.

It will also be appreciated that two biomedical balls with one or more of the balls provided with one or more sensors may be clustered together to form a biomedical device that provides expanded three dimensional monitoring. The cluster-type device allows for placement of even more sensors at critical locations invasively or non-invasively, for

increased integrity, redundancy, 3-D monitoring, and/or monitoring of a more comprehensive set of physiological activities.

It will also be appreciated that ball semiconductor IC may be powered with any of the power supply means disclosed in the copending applications herein referenced.

It will be still further appreciated in certain instances where the ball can be inserted onto a catheter, guidewire, needle stylet, that direct electrical connections may be made from the ball to a remote CPU. In this event, communication would be by hardwire as opposed to wireless techniques. In still another embodiment, a ball adapted with both hardwire and wireless links to a remote computer are possible.

Having described a number of embodiments for spherical semiconductor ICs--implemented as transducers for both sensor and actuator applications--to illustrate some of the wide variety of possible applications of implantable devices, the electrical structural and functional details of the spherical semiconductor ICs that are typically common to these embodiments will now be described.

For example, in one class of alternate embodiments there is provided an epicardial lead utilizing the principles of the present disclosure that provides the ability to be implanted within the myocardium of an individual's heart with an anode and a cathode that are separated therefrom by a predetermined distance. Interior to the epicardial lead is circuitry for processing information and generating a stimulus to the myocardium and for sensing electrical potentials in the myocardium. It is to be appreciated that the epicardial lead embodiment is illustrative of both sensor and actuator functions of a transducer provided on a spherical semiconductor IC according to the present disclosure. The epicardial lead includes a transceiver for allowing information to be received from an exterior location and transmitted thereto, the exterior location exterior to the human body and operable when proximate to the epicardial lead. Additionally, the epicardial lead can be a passive device wherein all power therefore is received form the external device. These features are described hereinbelow.

Referring now to FIGURE 16, the basic circuit functions of an epicardial lead are illustrated. Semiconductor ball 1610 includes an antenna/coil 1611, which serves the dual purpose of receiving signal energy from a central processing unit 1620 and transmitting signal energy thereto. The signal energy may be received by the antenna/coil 1611 by inductive coupling if the central processing unit 1620 is sufficiently close to the ball 1610. Alternatively, electromagnetic waves can be used to transmit power from the central processing unit 1620 to the ball 1610, whereby the magnetic field component of the electromagnetic wave induces a current in the coil 1611 in accordance with known techniques. The power signal received by the antenna/coil 1611 is rectified and smoothed by a radio frequency rectifier smoother circuit 1612. The output of the circuit 1612 is connected to a DC power storage device 1613, such as a capacitor. Such capacitor might also perform a waveform smoothing function. A voltage regulator 1614 is used to make the DC voltage stable regardless of the distance between the central processing unit 1620 and the ball 1610.

The ball 1610 includes the impulse generator, anode and cathode portions of the electrode, and flanking electrodes which are co-labeled in this diagram as transducer 1615 and may function either as sensors or actuators. In this particular example, the impulse generator functions as an actuator and the anode, cathode, and flanking sensors function as electrical sensors. Such semiconductor electrical sensors and impulse generators are known in the art and can be adapted to fabrication on a spherical semiconductor substrate as described hereinbelow in conjunction with FIGURE 17.

Returning to FIGURE 16, an analog-to-digital converter 1605 is used to convert the electrical signal sensed by the electrodes 1615 to a signal that can be transmitted out to the central processing unit 1620. The converter 1605 can be part of the transducer 1615, such as a variable capacitor for generating a signal depending upon the variations in capacitance. Control logic 1616, which can be part of an on board processor that controls not only the converter 1605 but also circuitry on the ball 1610, is provided in accordance with known techniques.

A radio frequency oscillator 1617 generates a radio-frequency carrier signal at a predetermined frequency in the radio frequency band. A radio frequency modulator 1618

modulates the output of the converter 1615 onto the carrier frequency signal. The resulting modulated signal is amplified by a radio frequency amplifier 1619, and then transmitted to the outside through the antenna/coil 1611. Further details of the preferred coil are described in the aforementioned commonly assigned U.S. Provisional Patent Application Serial No. 60/110,103 filed November 25, 1998 and entitled *MINIATURE SPHERICAL-SHAPED SEMICONDUCTOR WITH TRANSDUCER.*

An external central processing unit 1620 includes an antenna/coil 1621 that serves the dual purpose of generating the electromagnetic wave for transmitting power to the ball 1610, and receiving the radio frequency data signal transmitted by the ball 1610. It is preferred that the frequency of the electromagnetic wave that is output by the antenna/coil 1621 is different from the carrier frequency generated by the radio frequency oscillator 1617. A radio frequency amplifier 1622 is used to couple the electromagnetic wave for power transmission to the antenna/coil 1621. Radio frequency oscillator 1623 determines the frequency of the electromagnetic wave that is emitted by the central processing unit 1620. The data received by the antenna/coil 1621 is detected by a radio frequency detector 1624 and then amplified by a radio frequency amplifier 1625. Preferably, the converter 1626 converts the signal from the radio frequency amplifier 1625 to a digital signal, which in turn is input to control logic 1627. The control logic 1627 may be a smaller central processing unit to interface with the main central processing unit 1620. The control logic 1627 extracts the data from the signal received by the central processing unit 1620 from the ball 1610 and displays that information on a suitable display 1628, such as a CRT screen.

The technique for transmitting data from the ball 1610 to the main central processing unit 1620 using the carrier frequency generated by the radio frequency oscillator 1617 can be in the form using any suitable modulation and protocol. For example, the modulation can be AM, FM, PM, FSK or any other suitable modulation technique.

Those skilled in the art will recognize that the described epicardial pacing electrode can be employed to both stimulate the myocardium electrically as well as to detect myocardial electrical activity. Control of the epicardial electrode is via wireless remote

frequency eliminating problems with infections which gain access to the mediastinum via the trans-thoracic epicardial wires currently in use. Moreover, poor connection with the current wires to the monitor box can result in epicardial lead sensing and pacing malfunction.

Referring now to FIGURE 17, there is illustrated a schematic block diagram of the epicardial lead 1713 and the remote system for the powering/detection operation. The epicardial lead 1713, as described hereinabove, is operable to provide two output interfaces, an output pad 1700 as an anode and an output pad 1702 as a cathode, for interfacing with the cardiac muscle tissue. The spacing between these two pads or contacts 1700 and 1702 is approximately 0.5 cm. The illustrated embodiment of FIGURE 17 is that associated with a "passive" system, which term refers to the fact that there is no battery associated therewith. In order to operate the system, there is provided an inductive coupling element 1704 in the form of an inductor, which is operable to pick up an alternating wave or impulse via inductive coupling and extract the energy therein for storage in the inductive element 1704. This will create a voltage across the inductive element 1704 between a terminal 1706 and a terminal 1708. A diode 1710 is connected between the node 1708 and a node 1712, with the anode of diode 1710 connected to node 1708 and the cathode of diode 1710 connected to a node 1712. Typically, the diode 1710 will be fabricated as a Schottky diode, but can be a simple P/N semiconductor diode. For the purposes of this embodiment, the P/N diode will be described, although it should be understood that a Schottky diode could easily be fabricated to replace this diode. The reason for utilizing a Schottky diode is that the Schottky diode has a lower voltage drop in the forward conducting direction.

The diode 1710 is operable to rectify the voltage across the inductive element 1704 onto the node 1712, which has a capacitor 1714 disposed between node 1712 and node 1706. Node 1712 is also connected through a diode 1716 having the anode thereof connected to node 1712 and the cathode thereof connected to a node 1718 to charge up a capacitor 1720 disposed between node 1718 and 1706. The capacitor 1720 is the power supply capacitor for providing power to the epicardial lead 1713. The capacitor 1714, as will be described hereinbelow, is operable to be discharged during operation of the system

and, therefore, a separate capacitor, the capacitor 1720, is required for storing power to power the system.

The node 1712 is connected to the anode of a diode 1722, the cathode thereof connected to a node 1724. A main capacitor 1726 is connected between node 1724 and node 1706. The capacitor 1726, as will be described hereinbelow, is operable to provide the primary discharge energy to the myocardium via the output pad 1700, the anode of the epicardial lead 1713. This node 1724 is connected to one side of the gate/source path of a drive transistor 1728, the other side thereof connected to the output pad 1700. The gate of drive transistor 1728 is connected to the output of a switch control circuit 1730. Drive Transistor 1728 is operable to be turned on for a short period of time to connect to the top plate of capacitor 1726 to the output pad 1700 and subsequently, to conduct current to the myocardium.

In addition to transmitting energy out on pad 1700, there is also provided a sense transistor 1731 which has one side of the gate/source path thereof connected to the output pad 1700 and the other side thereof connected to a node 1732. The gate of sense transistor 1731 is connected to the output of the switch control 1730. Node 1732 is connected to the input of a buffer 1734 to generate an analog signal output thereof which is then converted with an analog-to-digital converter 1736 to a digital value for input to a central processing unit (CPU) 1738. The CPU 1738 is operable to receive and process this digital input voltage. A clock circuit 1740 is provided for providing timing to the system. A memory 1739 is provided in communication with the CPU 1738 to allow the CPU 1738 to store data therein for later transmittal back to the remote location or for even storing received instructions. This memory 1739 can be volatile or it can be non-volatile, such as a ROM. For the volatile configuration, of course, this will lose all information when the power is removed.

The CPU 1738 is operable to provide control signals to the switch control 1730 for turning on the drive transistor 1728 or the sense transistor 1731 at the appropriate time. Typically, the drive transistor 1728 is controlled to turn on for a period of approximately 0.5 microseconds 60-80 times per minute. Once drive transistor 1728 is turned off, then sense transistor 1731 can be turned on. Alternatively, sense transistor 1731 could be a

pass-through circuit such that the CPU 1738 can always monitor the voltage on the output pad 1700. However, it is desirable with the sense transistor 1731 and the sensing operation to sense depolarization in the myocardium after an output voltage has been provided thereto for a short duration of time.

In order to communicate with the CPU 1738 for transferring data thereto and for allowing the CPU 1738 to transfer data therefrom, a receive/transmit circuit 1742 is provided for interfacing to node 1712 to a resistive element 1744. This allows radio frequency (RF) energy to be transmitted to node 1712. It is important to note that the semiconductor junction across diode 1710 is a capacitive junction. Therefore, this will allow coupling from node 1712 to node 1704. Although not illustrated, this could actually be a tuned circuit, by selecting the value of the capacitance inherent in the design of the diode 1710. In any event, this allows an RF connection to be provided across diode 1710 while allowing sufficient energy to be input across conductive element 1704 to provide a voltage thereacross for rectification by the diode 1710 and capacitor 1714. Typically, the operating frequency of this connection will be in the MHz range, depending upon the design of which a variety are possible. For example, some possible designs are illustrated in U.S. Patent No. 4,333,072 and U.S. Patent No. 3,944,928, which are incorporated herein by reference. With these types of systems, power can continually be provided to the node 1712 and subsequently to capacitors 1720 and 1726 to allow power to be constantly applied to the epicardial lead. The diode 1722 may not be required in order to provide the sufficient charge to capacitor 1726, but some type of isolation is required between the capacitor 1726 and the capacitor 1720. Voltage regulation may also be required in order to provide a shaped pulse on the output pad 1700. This could be provided by the switch control 1730.

The remote system which is disposed external to the body and proximate to the epicardial lead 1713 includes an inductive element 1750 which is operable to be disposed in an area proximate to the skin exterior to the body in the proximity of the epicardial lead 1713. The inductive element 1750 is driven by a driving circuit 1752 which provides a differential output that is driven by an oscillator 1754. This will be at a predetermined frequency and power level necessary to couple energy from inductive element 1750 to inductive element 1704. Since this is an external system, the power of the oscillator can be

set to a level to account for any losses through the body tissues. To allow information to be transmitted, a modulation circuit 1756 is provided which is modulated by a transmitter signal in a block 1758 that allows information to be modulated onto the oscillator signal 1754, which oscillator 1754 provides a "carrier" signal. However, it should be understood that the information that is transmitted to the epicardial lead 1713 could merely be date information whereas the CPU 1738 could operate independent of the information being transmitted to provide the correct timing and wave shape for the output pulses. Alternatively, the entire control of the system may be provided by the transmit signal 1750 and the information carried thereon, because power must be delivered to the illustrated embodiment when there is a lack of an independent power source in the epicardial lead 1713.

The information received from the epicardial lead 1713 is modulated upon the oscillator signal driving the inductive element 1750. This information is extracted therefrom via a detector 1760 which has the output thereof input to a first low pass filter 1762 and then to a second low pass filter 1764. The output of low pass filters 1762 and 1764 are compared with a comparator 1766 to provide the data. The filter 1762 will provide an average voltage output, whereas the filter 1764 will provide the actual digital voltage output. The output of the comparator 1766 is then input to a CPU 1770 which also is powered by the oscillator 1754 to process the data received therefrom. This can be input to a display 1772.

Referring now to FIGURES 18a-18c, there are illustrated alternate embodiments for the transmit/receive operation. In FIGURE 18a, there is provided an oscillator 1800 which drives an external inductive element 1802 which may be utilized to couple both electrical power and information or data. Typically, there is some type of load 1804 disposed across the inductive element 1802. A separate inductive element 1806, inductively coupled to inductive element 1802, is provided on the epicardial lead 1713 of FIGURE 17. Voltage generated across the inductive element 1806, connected between a node 1808 and a node 1810 is applied across rectifier 1812 connected between node 1808 and a power node 1814. A power supply capacitor 1816 disposed across node 1814 and node 1810 stores the rectified voltage for use by the circuit. Similarly, a rectifier 1818 is connected between the node 1808 and a node 1820 which is connected to one side of a

main "surge" capacitor 1822. The other side of capacitor 1822 is connected to node 1810. This capacitor 1822 is similar to the main "surge" capacitor 1726 in FIGURE 17. The switch transistor 1728 is provided for connecting the node 1820 to the output pad 1700.

The receive operation in the embodiment illustrated in FIGURE 18b utilizes a separate inductive element or antenna 1824 in the epicardial lead 1713, which is operable to be connected between nodes 1809 and 1810. Node 1809 is capacitively coupled to a transmit node 1830 with a capacitor 1832, the capacitor 1832 being a coupling capacitor. A transmitter 1834 is provided for transmitting received data from a line 1836 to the node 1830 which is then coupled to the node 1809 to impress the RF signal across the inductive element 1824.

A corresponding inductive element 1840 is disposed on the external remote controller, which inductive element 1840 is operable to be disposed proximate to the inductive element 1824 for inductive coupling therewith, but external to the body having the epicardial lead 1713 implanted therein. The inductive element 1840 operates as a "pick-up" element to receive information, i.e., to function as an antenna, providing the received signal to a receiver 1842. The structure of FIGURE 18b is a separate structure, such that node 1809 is isolated from node 1808, the power receiving node illustrated in FIGURE 18a. However, it should be understood that harmonics of the oscillator 1800 may be coupled into the inductive element 1806. These harmonics may be tuned out by using a tuning element 1844 on the epicardial lead 1713 disposed across inductive element 1824 and also a tuning element 1846 disposed across the inductive element 1840, i.e., the antenna.

Referring now to FIGURE 18c, there is illustrated a simplified schematic diagram of the transmit embodiment. The epicardial lead 1713 of FIGURE 17 has associated therewith a separate receive antenna shown as an inductive element 1850 disposed between a node 1810 and a node 1852. Node 1852 is capacitively coupled to a receive node 1854 with a coupling capacitor 1856. A receiver 1858 is provide for receiving the information transmitted thereto and providing on the output thereof data on a data line 1860. The receiver 1858 is operable to receive the RF signal, demodulate the data therefrom, and provide digital data on the output 1860. External to the human body

having the epicardial lead 1713 implanted therein is a transmitter 1862 which is operable to impress a signal across an external inductive element 1864. The inductive element 1864, tuned with a tuning element 1866 basically provides for coupling the RF energy with inductive element 1850. A corresponding tuning element 1868 is provided on the epicardial lead 1713 and disposed across inductive element 1850. The inductive element 1850 and the inductive element 1864, one being inside the body and the other being external to the body function as the antennae for coupling RF signal energy across the interface between the epicardial lead 1713 and the central processing unit 1620.

Referring now to FIGURE 19, there is illustrated a cross-sectional view of the semiconductor device in the form of the spherical IC which has been "planarized" to remove the curvature thereof for discussion purposes herein. The semiconductor substrate is noted as a reference numeral 1900 and has disposed thereon various integrated circuits. In general, the semiconductor structure shown in FIGURE 19 represents an exemplary implementation of the main capacitor 1822, the diode 1818 and the transistor 1828 illustrated in FIGURE 18a. During fabrication, multiple layers of conductive material are disposed on the substrate separated by insulating oxide layers. These can be polycrystalline silicon layers or they can be metal layers.

In the disclosed embodiment of FIGURE 19, the first step in the process is to form active areas. A first active area is defined for forming the transistor 1928. This transistor 1928 is formed by first defining an active area 1904 and then depositing a thin layer of gate oxide thereover by conventional techniques. A gate electrode 1906 is then formed by depositing a layer of polycrystalline silicon on the substrate, patterning and etching the substrate to define the gate electrode 1906 separated from the surface of the silicon by a gate oxide layer. The edges of the gate electrode 1906 are then utilized to form source/drain implants 1908 on either side thereof. Disposed therebetween is a channel region. Similarly, during the processing in a P-type substrate, wherein the source/drain implants 1908 are N-type substrate material, an N-type implant region 1910 is formed followed by the formation of a P-implant region 1912 therein with an N-type contact region 1914 disposed within the region 1912. The region 1912 and the region 1914 essentially form a PN diode, the diode 1918. Once the active devices have been fabricated, another layer of polycrystalline silicon is disposed onto the substrate and etched to form

various layers. One structure is the a lower capacitor plate 1918, over which is deposited a layer of oxide 1920. This is the capacitor dielectric oxide layer. This layer of oxide 1920 may be deposited to as thin a layer as permitted by the process technology without resulting in a significant amount of defects which might destroy the quality of the resulting capacitor. After this structure 1918 is formed, typically from a second layer of polycrystalline silicon or even from the first layer of polycrystalline silicon that was utilized to form the gate electrode 1906, a subsequent process step will form a metal layer 1924 thereover. As is well known, capacitance varies inversely with the thickness of the dielectric. Thus, the effective area of the capacitor and the thickness of the dielectric and the type of material utilized as the dielectric will define the capacitor value. Typically, a dielectric layer thickness of between 300Å to 500Å can be deposited for the gate oxide. Various techniques can provide a silicon dioxide deposition on the order of 100Å. However, the thinner the capacitor dielectric layer, the more susceptible a large area capacitor is to processing problems which may result in a large number of defects in the capacitor. These are typically manifest as small conductive "shorts" between the layer 1924 and the structure 1918.

Prior to the formation of the structure 1924, vias 1926 and 1928 are formed through oxide layer 1920 previously deposited to expose a portion of the N-region 1914 and also a portion of a contact structure 1930 that is the conductive layer contacting the source/drain region 1908 of the transistor 1928. The vias 1926 and 1928 are then filled with a conductive plug of polycrystalline silicon or metal to provide a conductive connection between one side of the upper capacitor plate formed from the structure 1924 to the diode 1918 and the transistor 1904. The other side of the transistor 1928, the source/drain region 1908, is connected to an opposite side contact 1936 which will connect to the output pad 1700.

With the structure of FIGURE 19, there is provided a capacitor in series with a diode. Although not illustrated, the structure 1918, comprising the lower plate of the capacitor, is connected to the ground node which constitutes the output pad 1702 of FIGURE 17. The area of this structure 1918 must be substantially the same as that of the upper structure 1924, the effective area being that of the overlap between the two structures. The plate structures comprise a very large portion of the surface of the

spherical IC to provide a sufficient amount of capacitance. For the present application of a pacemaker, the capacitor must store enough energy to deliver approximately 25 micro joules of energy to the surrounding myocardium. This can be accomplished by increasing the area of the capacitor, decreasing the thickness of the capacitor dielectric or increasing the voltage across the capacitor (the stored energy being directly proportional to the square of the voltage).

Referring now to FIGURE 20, there is illustrated a cross-sectional view 2000 of the output pad 1700 of FIGURE 17. In general, the output pad 1700 is required to provide a conductive interface between the transistor 1728 and, for example, the myocardium muscle. This therefore requires some type of metallic interface that is non-reactive. Such an interface would require a metal such as gold, platinum and the like. In the disclosed embodiment, gold would be provided.

After the formation of the upper metal layer via a deposition technique with metal such as aluminum or copper, a passivation layer of oxide 2002 is disposed over the substrate 1100 to basically prevent oxidation of the metal layers and protect the semiconductor circuits in general. The contact layer 1936 extends beyond the active region 1904 to an output pad region 2004 and is separated from the active region 1904 by a layer of field oxide 2008 or some type of isolation oxide. There may be some type of channel stop implant disposed below the field oxide layer 2008. The contact 1936 extends from the source/drain implant 1908 to the region 2004. This contact 1936 is required to be fairly conductive. Typically, polycrystalline silicon is not of sufficient conductivity to meet this requirement. Therefore, some type of polysilicide process will be required, wherein the upper surface is converted to some type of silicide such as titanium disilicide to lower the surface resistivity thereof. Alternatively, a metal layer could be provided which is connected to the contact region 1936.

Once the contact 1936 is formed and the passivation layer 2002 is disposed over the entire structure, vias 2006 are formed therein. These vias are then filled with metallic plugs 2008 by forming a layer of metal over the substrate and then etching the substrate to remove the undesired portions. The metal plugs 2008 may be formed of metal such as aluminum or gold. If they were formed of gold, this would allow for soldering if they

were to be used as contacts. However, in this context, these plugs 2008 are utilized for conductivity purposes. Therefore, an aluminum plug would be sufficient if it were covered with a thin layer of gold to render the aluminum non-reactive and prevent oxidation thereof. Alternatively, in the disclosed embodiment, the plug may, of course, be gold. However, it should be understood that any type of non-reactive metal could be utilized as long as the surface thereof is sufficiently non-reactive and the conductance of the plug is sufficiently high to result in a low resistance path between the exterior of the spherical IC and the capacitive plate 1924. The reason for this is that the stored charge must be discharged into a resistance as low as 500 Ohms and any significant resistance disposed between the upper plate of the capacitor 1124 and the exterior must be minimized.

Referring now to FIGURE 21, there is illustrated a perspective view of the spherical IC 26, wherein the inductive element 1704 of FIGURE 17 is illustrated as being strips of conductive material wrapped around the exterior of the spherical IC 26. The inductive element 1704 described hereinabove with respect to FIGURE 17, is formed of a conductive strip wrapped many times around the spherical IC 26. The length of these wires depends upon the receive characteristics that are required. As described hereinabove with reference to FIGURES 18a-18c, there could be multiple conductive strips, each associated with a receive function, a transmit function or a power function, or they could all share one single conductive element or strip. On one end of the spherical IC 26, as described hereinabove, there is provided an anode output pad 1210 having conductive balls 2112 associated therewith of material such as gold for communicating with the biological medium surrounding the sensor. On the other end thereof are provided interfacing interconnect balls 2122.

Referring now to FIGURE 22, there is illustrated a cross-sectional diagram of the surface of the spherical IC 26 illustrating the conductive strips forming the inductive element 1704 of FIGURE 17. The conductive strips are identified by reference numeral 2210 which are spaced above the surface of the IC by a predetermined distance and separated therefrom by a layer of silicon dioxide. The passivation layer is then disposed over the upper surface of the conductive strips 2210. The conductive strips 2210 can be fabricated from polycrystalline silicon but, it would be preferable to form them from the upper metal layer to result in a higher conductivity strip. This will allow the strips 2210 to

be narrower and separated from each other by a larger distance. This separation would reduce the amount of capacitance therebetween.

One end of the strips 2210 is connected to a diode structure. The diode structure is formed of an N-well implant region 2214 into which a P-well implant region 2216 is disposed, and an N-well implant region 2218 disposed within the P-well implant region 2216. This forms a PN diode where one end of the conductive strips 2210, a conductive connection 2220, is connected to the P-well 2216 implant region and a conductive layer 2222 is connected at one end to the N-well implant region 2218. This conductive layer or strip 2222 extends outward to other circuitry on the integrated circuit and can actually form one plate of the capacitor 1714 shown in FIGURE 17. Since it needs to go to a capacitor directly, a lower plate 2224 formed of a layer of polycrystalline silicon or metal in a double-metal process, could be provided separated therefrom by a dielectric layer of oxide.

Referring now to FIGURE 23, there is illustrated a side view of an alternate embodiment utilizing additional circuitry or structure in the region between the spherical IC 25 and the spherical IC 26. In one application, an epicardial lead requires two primary structures the epicardial lead 1713 of FIGURE 17 requires two primary structures, a power supply generating structure for storing a power supply voltage such that diodes must be provided for receiving and rectifying a large amount of power and charging up a power supply capacitor, in addition to a main "surge" capacitor for providing a relatively large amount of pulsed energy to the myocardium. The space between the spherical IC 25 and the spherical IC 26 may contain either a battery or a capacitor represented by a structure 2310 as illustrated in the embodiment of FIGURE 23. This is disposed between the supporting structure 2312 and 2318.

Referring now to FIGURE 24, there is illustrated a schematic block diagram of the epicardial lead 1713 of FIGURE 17 illustrating the use of a battery. A battery 2410 is provided which is connected to a capacitor 2412. The capacitor 2412 could be identical to the capacitor 1726 of FIGURE 17 in that it could be formed on the surface of the spherical IC 25 or it could actually be part of the structure 2310 shown in FIGURE 23. The battery 2410 is provided across the capacitor 2412 to provide sufficient charge therefor.

Additionally, the capacitance 2412 could actually be the capacitance of the battery 2410. Additional structure could be provided for powering the CPU 1738 and the other circuitry on the chip from the battery 2410. As such, there would only be required a smaller inductive element 2414 and a capacitor 2416 to allow the receive/transmit block 1742 to receive/transmit information from and to the remote exterior station. It is to be appreciated that the epicardial lead embodiment depicted in FIGURES 16-24 and described hereinabove is illustrative of both sensor and actuator functions of transducers which may be provided using the spherical semiconductor IC technology of the present disclosure.

Turning now to another class of alternate embodiments, the application of spherical semiconductor ICs to sensing chemical parameters and variables within biological tissues will now be described. Included in this class of embodiments are the pH sensors, ionic activity or concentration sensors and sensors for all kinds of substances in the human body such as glucose, carbohydrates, proteins, sugars, enzymes, hemoglobin, lipids and phospholipids, neurotransmitters, cell integrins and other cell receptors. These are just some of the possible substances that may be monitored by the spherical semiconductor IC devices of the present disclosure described herein.

Referring now to FIGURE 25, there is illustrated an embodiment having a hydrogel 2500 which is covalently attached to the surface of the semiconductor ball IC (or, in the alternative, a ball semiconductor IC or merely "ball") configured as a sensor 10 as also shown hereinabove in FIGURES 1 through 4. This hydrogel 2500 is pH sensitive, and undergoes very large changes in volume with small changes in local pH. This hydrogel 2500 changes volume manyfold over a small pH change. The hydrogel 2500 is covalently receptive to certain biologically active enzymes such as glucose oxidase. This enzyme catalyzes the reaction

$$\text{Glucose} + 2\,H_2O + O_2 - \text{Gluconic Acid}^- + H_3O^+ + H_2O_2 \qquad (1)$$

Therefore, the change in acid concentration (measurable as a pH change) is directly proportional to the glucose concentration. This allows the hydrogel 2500 then to serve as a very sensitive glucose sensor. With the appropriate degree of cross-linking, the gel 100 can actually exert a contractile force on the semiconductor ball sensor 10 on the order of

10^4 dynes/cm^2. This contractile force is large enough to be measured as a pressure exerted on the surface of the semiconductor ball sensor 10. This embodiment can therefore detect small changes in the local pH caused by the oxidation of glucose by the enzyme glucose oxidase. To prevent shifts in pH due to other reasons from giving a false reading, an aggregate of two semiconductor ball sensors 10 will always be used clinically, where one of the semiconductor ball sensors 10 contains the glucose oxidase 110 enzyme and the other does not. Therefore, by examining the difference between the two ball sensors 10, the effects due to the presence of glucose can be isolated.

Referring now to FIGURE 26, there is illustrated another embodiment of a ball semiconductor sensor 10 that has at least two osmotic pressure sensors provided by osmotic chambers 2600 and 2604, which are located on the same ball sensor 10. A semi-permeable membrane 2601 is permeable to both water and glucose. A semipermeable membrane 2602 is water permeable, but not glucose permeable. An electrode 2603 is connected between the osmotic chamber 2604 and the differential amplifier 2606. The osmotic chamber 2604 includes water, salts, glucose and other small molecules. The osmotic chamber 2600 includes water and salts only, and is connected to the differential amplifier 2606 by the electrode 2603. Two electrodes 2605 are disposed on the outer periphery of the ball sensor 10, and connected to respective ones of the semi-permeable membranes 2601 and 2602.

Referring now to FIGUREs 27 and 28, there is illustrated respectively a graph indicating the volume of the hydrogel as a function of the change in pH in FIGURE 27, and a graph showing the anticipated sensed pressure as a function of pH changes in FIGURE 28, which will be proportional to graphing pressure changes as a function of glucose concentration if glucose oxidase is attached to the hydrogel. Because of the rapid rate of change of volume with respect to pH, this embodiment provides a near step function output as shown in FIGUREs 27 and 28. Therefore, this sensor is ideal to drive such devices as, illustratively, an insulin pump, giving sharp on/off signals to the pump mechanism thus providing unambiguous control thereof.

Referring now to FIGURE 29, there is illustrated another embodiment of a sensor portion of the ball semiconductor sensor 10 (of FIGURES 1 through 4 and FIGURE 25)

having a well for electrochemical detection of glucose using a pH sensitive hydrogel coupled with an electrically conductive polymer. The pH sensitive hydrogel cross-linked with an electrically conducting polymer 2980 that also swells in water, for example, polyaniline. The enzyme glucose oxidase is covalently attached to this hydrogel composite 2980, which is then attached to the surface of an electrode 2960 at the bottom of a well 2970 in the surface of the semiconductor which semiconductor is formed upon substrate 2922. A semipermeable membrane 2940 is attached across the top of the well 2970, forming a tightly sealed electrochemical chamber 2970. The hydrogel composite 2980 is comprised of a pH sensing hydrogel, an electrically conductive polymer 2980 and a glucose oxidase. The electrode 2950 and an electrode 2960 together form a parallel plate capacitor. The electrode 2950 is attached to the semipermeable membrane, forming a parallel plate capacitor, which is connected to an LRC circuit (not shown in FIGURE 29). This LRC circuit (not shown in FIGURE 29) preferably detects changes in glucose levels by shifts in the natural frequency of the circuit. As glucose diffuses into the chamber, it will react with the glucose oxidase, change the pH within the chamber, and hence change the volume of the hydrogel composite 2980. As the volume of the hydrogel composite 2980 changes, the electrically conducting polymer is brought nearer the top electrode. This changes the effective thickness of the capacitor dielectric, which is detected as a change in the frequency of the LRC circuit. Therefore, changes in the glucose level are directly measured as frequency changes in the electronic circuitry of the semiconductor ball 10.

Turning now to another class of alternate embodiments, the application of spherical-shaped semiconductor ICs to sensing pressure changes within biological media will now be described. Included in this class of alternate embodiments are pressure changes in cardiac arterial, cerebralspinal (or CSF) or cerebral, respiratory and sinus locations, skeletal or other weight-bearing locations, or in locations where sensing pressure changes provides information regarding the movement of structures such as vocal cords, rib cage and numerous other muscular and skeletal structures.

Referring now to FIGURE 30, an illustrative transducer 3012 is shown in schematic cross section and represents one of many different possible implementations of the transducer 3012 of FIGURE 1. The transducer 3012 is formed atop a semiconductor

substrate 3022, which is preferably doped P-type and serves as the electrical ground for the circuits on the sensor ball 10 described hereinabove. A dielectric layer 3024 lies on the outer surface of the substrate 3022 and overlies a cavity 3026 cut down into the substrate 3022. Lying atop the dielectric layer 3024 and juxtaposed with the cavity 3026 is an electrode 3028. Extending along a surface portion of the substrate 3022 and beneath the cavity 3026 is a first N-type region 3033, which may be formed by selectively introducing a dopant such as phosphorus by a conventional technique such as ion implementation. The region 3030 has a portion 3031 to the left of the cavity 3026 and a portion 3033 underneath the cavity 3026. A second N-type region 3032 is provided at a surface portion of the substrate 3022 as shown to the right of the cavity 3026. An extension 3034 of the electrode 3028 makes contact to region 3032 through an opening in the dielectric layer 3024.

With reference to FIGURE 31, a possible layout for the electrode 3028 and cavity 3026 therebelow is illustrated. The extension 3034 is shown extending out to a contact point 3036 where contact to the N-type region 3032 is made through the dielectric layer 3024, as depicted in FIGURE 30.

It will be appreciated that the structure of the transducer 3012 of FIGURES 30 and 31 forms a variable capacitor with the electrode 3028 serving as one capacitor plate and the portion 3033 of N-type region 3030 beneath the cavity 3026 serving as the other capacitor plate. The N-type regions 3030 and 3032 extend to points of interconnection (not shown) with other circuitry as will be described below with reference to FIGURE 32. The variable capacitor is responsive to changes in pressure applied to the electrode 3028. The top surface of electrode 3028 is exposed to a medium, such as a fluid, that exerts a variable pressure on the electrode 3028. The force of this pressure is applied by the electrode 3028 to the underlying portion of the dielectric layer 3024, designated 3025 in FIGURE 30, which serves as a diaphragm. The dielectric diaphragm 3025 is sufficiently flexible to respond to the force of the pressure variations by moving down slightly into the cavity 3026 with increasing pressure and back up to the position shown at a base-line pressure, such as atmospheric pressure. It will be appreciated that the capacitance of the capacitor defined by the plates 3028 and 3033 will thus vary as a function of the pressure

variations seen by the transducer 3012. The extension 3034 is sufficiently thin and narrow that it will flex as the dielectric diaphragm 3025 flexes up and down.

For the transducer application of FIGURES 30 and 31, the ball 10 is preferably about one millimeter in diameter. For other applications, it may be possible to make the diameter much smaller, limited only by the process technology and other practical considerations.

Techniques for producing a diaphragm above a cavity that can be used to implement the structure generally shown in FIGURE 30 in a more specific structure are known in the art, such as are disclosed in U.S. Patent No. 4,665,610, which is hereby incorporated by reference. It will be appreciated that other implementations of a pressure transducer that are known in the art can be employed as alternatives to the transducer 3012 of FIGURE 30.

With reference to FIGURE 32, other circuit elements of the transducer 3012 will be described. The variable capacitor, designated by the letter C, has its upper plate 3028 connected to an oscillator circuit 3040, and has its lower plate 3033 connected to the substrate 3022, which is indicated by the ground potential symbol. A resistor 3042, designated by the letter R, is connected in parallel with the capacitor C. The oscillator circuit 3040 provides an output 3044 that oscillates at a frequency that is a function of the product of the values of R and C. This phenomenon and specific circuitry for implementing an oscillator such as oscillator 3040 are well known. Accordingly, it will be appreciated that the oscillator output 3044 will oscillate at a frequency that is proportional to the capacitance of capacitor C, which varies with the sensed pressure variations as described above.

Turning now to yet another class of alternate embodiments, the application of spherical semiconductor ICs to sensing radiated phenomena within biological media such as X-rays, sound, light, heat and the like. Included in this class of sensors are imaging devices (X-ray, sonogram, light images from CCD sensors, infrared sensors, MRI and CAT scans, radioactivity sensing, doppler imaging, 3D imaging, and the like. A plurality of balls can be provided for a 3D reconstruction the site to which they have been applied.

Referring now to FIGURE 33, there is illustrated a conventional X-ray imaging apparatus utilizing a flat panel X-ray detector. A human body 3302 under examination is irradiated with X-rays emitted from an X-ray tube 3304, and X-rays transmitted through the human body 3302 are directed on to a flat panel X-ray detector 3306. The flat panel X-ray detector 3306, as will be described hereinbelow in more detail comprises a two-dimensional array of detector elements, each of which forms a picture element (pixel). Signals are output from the detector 3306 and fed to a CPU 3310 for assembling into an image for display on a display 3312. During processing, the CPU 3310 is operable to digitize the analog output of the X-ray detector 3306 and store the digital information in a memory 3314. As will also be described in more detail hereinbelow, the CPU 3310 is operable to modify the analog output from the detector 3306, store this information in the memory 3314 for later retrieval therefrom and subsequent display on the display 3312. Alternatively the CPU 3310 is operable to directly display the information on the display 3312 in real time. The flat panel display is only one embodiment. In another embodiment, a curvilinear display could be fabricated. This would allow the object being examined to be disposed adjacent to the surface at all points. This allows the object to have any point thereon disposed only a short distance from the surface of the display. Additionally, it should be understood that the objet being examined could be any type of object, a human or animal body, a plant or an inanimate object.

Referring now to FIGURE 34, there is illustrated a section view of the detector array 3306 illustrating a plurality of detector elements, which detector elements contain a plurality of pixels. The detector elements are all spherical elements or balls which utilize a spherical semiconductor device. A spherical semiconductor device is described in U.S. Patent Application Serial Number 5,955,776, issued September 21, 1999 referenced above.. There are four types of spherical detector elements provided. These are a top Spherical IC 3402, a center Spherical IC 3404, an edge Spherical IC 206 and a corner Spherical IC 208. Each of the Spherical ICs 3402, 3404, 3406 and 3408 has the potential of having a plurality of pixel elements disposed on the upper surface thereof. The top Spherical ICs 202 are disposed in an upper layer and the remaining Spherical ICs, the center Spherical IC 204, the edge Spherical IC 206 and the corner Spherical IC 208, are disposed in a second layer, which second layer is disposed on the surface of a substrate 210.

Referring now to FIGURES 35a-35d, there are illustrated top views of each of the Spherical ICs 3402-3408. In the Spherical IC 3402, illustrated in FIGURE 35a, there are illustrated ten pixels 3502 on the upper surface thereof. Each Spherical IC may typically be, e.g., one millimeter (mm) in diameter. The area of each of the pixels 3502 would then be approximately 500 microns^2. The pixels 3502 are illustrated in each of the FIGURES 35a-35d on three rows, a center row with four pixels 302, and an upper and lower row with three pixels 302 each. However, these pixels can be arranged in any manner desirable and do not necessarily need to be rectangular in shape. In the disclosed embodiment, all the pixels are illustrated as being somewhat along an array for fabrication purposes. In FIGURE 35b, there is illustrated a top view of the center Spherical IC 3404. Only two of the pixels 3502 in the center row and one each in the upper and lower rows are included. In FIGURE 35c, there is illustrated a top view of the edge Spherical IC 3406. In this view, there are only illustrated six pixels 3502, two from each of the rows on one side thereof. In the corner Spherical IC 3408, there are illustrated in FIGURE 35d eight of the pixels 3502, three from the top row, three from the center row and two from the bottom row. Again, the arrangement of pixels can be modified, depending on how much surface area is to be exposed from the bottom layer as a result of the arrangement of the top row.

Each of the pixels 3502 is sized such that the upper surface area of the Spherical IC is as completely covered as possible with the display area. This is to ensure that a large portion of the pixels 3502 are disposed on the very top surface of the Spherical IC.

Referring now to FIGURE 36, there is illustrated a cross-sectional diagram of one of the Spherical ICs 3402 illustrating one row of pixel elements 3502. FIGURE 37 illustrates a more cross-sectional view of each of the pixel elements 3502. Each of the pixel elements 3502 is comprised of a layer of amorphous hydrogenated silicon (a-Si:H) 3702 which is disposed under a layer of heavy metal 3704, which is molybdenum (Mo) to form a Schottky diode which allows detection of low energy X-rays. The layer of Si:H 3702 is disposed over a layer of N-type doped a-Si:H material 3706 which is disposed over a conductive layer 3708. The conductive layer 3708 is disposed on a silicon substrate 3710, which silicon substrate is provided by the Spherical IC described hereinabove. However, the placement and separation of the various pixels 3502 will be determined in part by the process technology which will define the minimum spacings between adjacent

elements on the surface of the semiconductor substrate 3710 in the form of the Spherical IC.

Referring now to FIGURE 38, there is illustrated a schematic diagram of the pixel 3502 as incorporated into a detection element. The pixel 3502 basically comprises a Schottky diode 3802 which has the cathode thereof connected to a bias voltage on a node 3804 and the anode thereof connected to a node 3806. In one embodiment, node 3806 is connected to one plate of a storage capacitor 3808, the other plate thereof connected to ground. The Schottky diode 3802 is operable to collect electrons for storage on the upper plate of the capacitor 3808. This storage of electrons results in an increase in the voltage across the plates of the capacitor 3808 which can later be transferred through a gate transistor 3810 to the input of a charge amplifier 3812 for output on an output node 3814.

The structure and operation of the Schottky diode 3802 is described in K. Aflatooni, A. Nathan, R.I. Hornsey, I.A. Cunningham, *A NOVEL DETECTION SCHEME FOR LARGE AREA IMAGING OF LOW ENERGY X-RAYS USING AMORPHOUS SILICON TECHNOLOGY*, Technical Digest, 9th Int. Conf. On Solid-State Sensors and Actuators, June 16-19, Chicago, 1997, pp. 1299-1302, which is incorporated herein by reference. In general, the Schottky diode is comprised of various layers, one being an anode contact and one being a cathode contact with the layer of a-Si:H material disposed therebetween. The contact thereof has a layer of heavily doped a-Si:H material disposed therein to establish ohmic contact. The top contact, the anode, is formed by the deposition of the heavy metal such as Mo. When the diode is reversed biased, i.e., there is a positive voltage disposed on the anode, this will result in a relatively low reverse bias current, which is a function of the area. Additionally, the reverse current can be affected by the reverse bias voltage, which may result in a time-dependent variation in the reverse current.

In general, it has been reported in the literature that X-ray sensitivity measurements for a 200μm^2 Schottky diode with a reverse bias of 2 volts, exhibits a collection of electron vs. the X-ray source voltage level kVp which will span the range 20keV to 100keV. At a source voltage of 50 kVp, the measured number electrons collected over a period of 500 ms is approximately $4x10^7$. At higher energies on the order of 100kVp, the measured electrons were approximately $2x10^8$. In general, the thickness of the a-Si:H layer will

affect a collection efficiency of electrons in the Schottky diode. However, once the intrinsic layer of thickness exceeds the maximum range of the electrons ($\approx 1\mu m$), the output signal will in general, saturate or decrease. This is due to the fact that the depletion layer no longer widens accompanied by an increased width of the neutral region. Increased width under these circumstances leads to a degradation in the number of collected electrons, particularly when the width of the neutral region exceeds the electron depletion layer.

Referring further to FIGURE 38, the electrons are allowed in this illustrative example, to be collected over a period of approximately 500ms (it being understood that this number can vary, depending upon the geometry and the processing technology) and then gated out from the node 3806 at a predetermined time. The amplifier 3812 is a high impedance amplifier that will not cause a significant discharge of the capacitor 3808. Therefore, an exposure would typically be effected by turning on the X-ray source 3304 for a period of 500ms and then sampling all of the capacitors 3808 in the detector array in a predetermined order.

Although the preferred embodiment has been described in detail, it should be understood that various changes, substitutions and alterations can be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

WHAT IS CLAIMED IS:

1. An implantable monitor circuit, comprising:

a substrate having a portion thereof configured with an arcuate surface;

a sensor disposed on said portion for sensing a quantitative condition of an adjacent medium and generating an electrical signal representative thereof; wherein

said substrate is capable of being disposed within a desired portion of a biological medium.

2. The apparatus of Claim 1, wherein said substrate is formed of semiconductor material.

3. The apparatus of Claim 2, wherein said semiconductor substrate is substantially spherical.

4. The apparatus of Claim 1, wherein said implantable monitor circuit further comprises:

a communication link coupled with said sensor.

5. The apparatus of Claim 4, wherein said communication link comprises:

a communication channel for exchanging information between said implantable monitor circuit and an external device.

6. The apparatus of Claim 4, wherein said communication link comprises:

a communication channel for delivering power to said implantable monitor circuit from an external device.

7. The apparatus of Claim 4, wherein said sensor and said communication link are disposed on said semiconductor substrate, forming thereon a monolithic circuit.

8. The apparatus of Claim 7, wherein said monolithic circuit further comprises:

a processor coupled to said communication link and to said sensor for generating said electrical signal.

9. An implantable monitor circuit, comprising:

a substrate having a portion thereof configured as an arcuate surface;

an actuator disposed on said portion for introducing an effect into an adjacent medium responsive to an electrical signal representing a desired stimulus to said adjacent medium; wherein

said substrate is capable of being disposed within a desired portion of a biological medium.

10. The apparatus of Claim 9, wherein said substrate is formed of semiconductor material.

11. The apparatus of Claim 10, wherein said semiconductor substrate is substantially spherical.

12. The apparatus of Claim 9, wherein said implantable monitor circuit further comprises:

a communication link coupled with said actuator.

13. The apparatus of Claim 12, wherein said communication link comprises:

a communication channel for exchanging information between said implantable monitor circuit and an external device.

14. The apparatus of Claim 12, wherein said communication link comprises:

a communication channel for delivering power to said implantable monitor circuit from an external device.

15. The apparatus of Claim 12, wherein said actuator and said communication link are disposed on said semiconductor substrate, forming thereon a monolithic circuit.

16. The apparatus of Claim 15, wherein said monolithic circuit further comprises:

a processor coupled to said communication link and to said actuator for generating said electrical signal.

17. An implantable monitor circuit, comprising:

a substrate having a portion thereof configured as an arcuate surface;

a transducer disposed on said portion for coupling a signal representative of a desired stimulus of or a quantitative condition of an adjacent medium; wherein

said substrate is capable of being disposed within a desired portion of a biological medium.

18. The apparatus of Claim 17, wherein said substrate is formed of semiconductor material.

19. The apparatus of Claim 18, wherein said semiconductor substrate is substantially spherical.

20. The apparatus of Claim 17, wherein said implantable monitor circuit further comprises:

a communication link coupled to said transducer.

21. The apparatus of Claim 20, wherein said communication link comprises:

a communication channel for exchanging information between said implantable monitor circuit and an external device.

22. The apparatus of Claim 20, wherein said communication link comprises:

a communication channel for delivering power to said implantable monitor circuit from an external device.

23. The apparatus of Claim 20, wherein said transducer and said communication link are disposed on said semiconductor substrate, forming thereon a monolithic circuit.

24. The apparatus of Claim 23, wherein said monolithic circuit further comprises:

a processor coupled to said communication link and to said transducer for generating an electrical signal corresponding to said coupled signal.

25. The apparatus of Claim 17, wherein said transducer comprises:

a sensor for sensing a quantitative condition of said adjacent medium and generating an electrical signal representative thereof.

26. The apparatus of Claim 17, wherein said transducer comprises:

an actuator for introducing an effect into said adjacent medium responsive to an electrical signal representing a desired stimulus to said adjacent medium.

27. The apparatus of Claim 8, wherein said electrical signal comprises a detection signal.

28. The apparatus of Claim 16, wherein said electrical signal comprises a control signal.

29. The apparatus of Claim 28, wherein said control signal comprises a stimulation signal.

30. The apparatus of Claim 28, wherein said control signal comprises a delivery signal.

31. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing pH in said biological medium and generating an electrical signal representative thereof.

32. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing partial pressure of gasses in said biological medium and generating an electrical signal representative thereof.

33. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of glucose in said biological medium and generating an electrical signal representative thereof.

34. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing concentrations of select ions in said biological medium and generating an electrical signal representative thereof.

35. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of select proteins in said biological medium and generating an electrical signal representative thereof.

36. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of select carbohydrates in said biological medium and generating an electrical signal representative thereof.

37. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of select enzymes in said biological medium and generating an electrical signal representative thereof.

38. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of select lipids in said biological medium and generating an electrical signal representative thereof.

39. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of select phospholipids in said biological medium and generating an electrical signal representative thereof.

40. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of cell integrins in said biological medium and generating an electrical signal representative thereof.

41. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of neurotransmitters in said biological medium and generating an electrical signal representative thereof.

42. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing levels of hemoglobin in said biological medium and generating an electrical signal representative thereof.

43. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing fluid pressure in said biological medium and generating an electrical signal representative thereof.

44. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing cerebrospinal fluid in said biological medium and generating an electrical signal representative thereof.

45. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing blood pressure in said biological medium and generating an electrical signal representative thereof.

46. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing rate of flow of fluid in said biological medium and generating an electrical signal representative thereof.

47. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing viscosity of fluid in said biological medium and generating an electrical signal representative thereof.

48. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing pressure in said biological medium and generating an electrical signal representative thereof.

49. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing stress of compression in said biological medium and generating an electrical signal representative thereof.

50. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing stress of tension in said biological medium and generating an electrical signal representative thereof.

51. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing temperature in said biological medium and generating an electrical signal representative thereof.

52. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing respiration in said biological medium and generating an electrical signal representative thereof.

53. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing contraction in said biological medium and generating an electrical signal representative thereof.

54. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing expansion in said biological medium and generating an electrical signal representative thereof.

55. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing position in said biological medium and generating an electrical signal representative thereof.

56. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing velocity in said biological medium and generating an electrical signal representative thereof.

57. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing heat in said biological medium and generating an electrical signal representative thereof.

58. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of energy in said biological medium and generating an electrical signal representative thereof.

59. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of ultraviolet energy in said biological medium and generating an electrical signal representative thereof.

60. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of visible light energy in said biological medium and generating an electrical signal representative thereof.

61. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of electromagnetic energy in said biological medium and generating an electrical signal representative thereof.

62. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of sound energy in said biological medium and generating an electrical signal representative thereof.

63. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of radio frequency energy in said biological medium and generating an electrical signal representative thereof.

64. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of radioactive energy in said biological medium and generating an electrical signal representative thereof.

65. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing emission of x-ray energy in said biological medium and generating an electrical signal representative thereof.

66. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing bioelectric signals in said biological medium and generating an electrical signal representative thereof.

67. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing electrocardiographic signals in said biological medium and generating an electrical signal representative thereof.

68. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing electroencephalographic signals in said biological medium and generating an electrical signal representative thereof.

69. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing electromyographic signals in said biological medium and generating an electrical signal representative thereof.

70. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing nerve conduction velocity in said biological medium and generating an electrical signal representative thereof.

71. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing color changes in blood in said biological medium and generating an electrical signal representative thereof.

72. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing antigens in said biological medium and generating an electrical signal representative thereof.

73. The circuit of Claim 1, wherein:

said sensor disposed on said arcuate surface is operable for sensing antibodies in said biological medium and generating an electrical signal representative thereof.

74. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting a controlled cardiac rhythm in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

75. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting a transcutaneous electrical nerve stimulation in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

76. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting a muscle stimulation in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

77. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting a prosthesis control in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

78. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting an optic nerve enhancement in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

79. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting an auditory nerve enhancement in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

80. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting an olfactory nerve enhancement in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

81. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting destruction of tumor cell tissue via heating energy in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

82. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting destruction of tumor cell tissue via chemotherapy in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

83. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting destruction of tumor cell tissue via radiation energy in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

84. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting destruction of tumor cell tissue via sound energy in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

85. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting application of laser ablative energy in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

86. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting medication delivery in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

87. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting actuation of a mechanical device in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

88. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting actuation of an electrical device in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

89. The circuit of Claim 9, wherein said actuator disposed on said arcuate surface is operable for effecting actuation of a pump to deliver medication in said biological medium responsive to an electrical signal representing a desired stimulus to said biological medium.

90. The circuit of Claim 1, wherein said sensor disposed on said arcuate surface is operable for sensing image signals representing conditions within said biological medium and generating an electrical signal representative thereof.

91. The apparatus of Claim 90, wherein said sensor comprises:
means responsive to emissions of x-ray imaging apparatus.

92. The apparatus of Claim 90, wherein said sensor comprises:
means responsive to emissions of computer assisted tomographic imaging apparatus.

93. The apparatus of Claim 90, wherein said sensor comprises:
means responsive to emissions of nuclear magnetic resonance imaging apparatus.

94. The apparatus of Claim 90, wherein said sensor comprises:
means responsive to emissions of sonogram imaging apparatus.

95. The apparatus of Claim 90, wherein said sensor comprises:
means responsive to emissions of Doppler scanning imaging apparatus.

96. The apparatus of Claim 90, wherein said sensor comprises:
means responsive to emissions of light wave scanning imaging apparatus.

97. The apparatus of Claim 90, wherein said sensor comprises:

means responsive to emissions of electron wave scanning imaging apparatus.

98. A circuit for implantation in a biological medium, comprising:

a semiconductor integrated circuit configured with an arcuate surface;

data processing means disposed on said arcuate surface for receiving to, storing in and transmitting from said circuit information including medical, personal and identification data for use upon access by an external device; wherein

said circuit is capable of being disposed within said biological medium.

99. The apparatus of Claim 98 wherein said access and said circuit's response thereto is performed using wireless communication.

100. The apparatus of Claim 99 wherein said wireless communication comprises:

data transmission via a modulated radio frequency link.

101. A spherical-shaped biomedical integrated circuit for biomedical applications.

102. The spherical-shaped integrated circuit of Claim 101 operable for physiological monitoring.

103. The spherical-shaped integrated circuit of Claim 101 operable for diagnostics.

104. The spherical-shaped integrated circuit of Claim 101 operable for imaging.

105. The spherical-shaped integrated circuit of Claim 101 operable for electronic patient monitoring.

106. The spherical-shaped integrated circuit of Claim 101 operable for stimulating physiological activity.

107. The spherical-shaped integrated circuit of Claim 101 operable for physiological therapy.

108. The spherical-shaped integrated circuit of Claim 101 operable for physiological treatment.

109. The spherical-shaped integrated circuit of Claim 101 operable for physiological robotics.

110. The spherical-shaped integrated circuit of Claim 101 operable for computerized physiological data processing.

111. The spherical-shaped integrated circuit of Claim 101 operable for physiological data tracking.

112. The spherical-shaped integrated circuit of Claim 101 operable for gene analysis.

113. The spherical-shaped integrated circuit of Claim 101 adapted to a catheter.

114. The spherical-shaped integrated circuit of Claim 101 adapted to a stent.

115. The spherical-shaped integrated circuit of Claim 101 adapted to a glove for use in physiological measuring.

116. A plurality of spherical-shaped integrated circuit of Claim 101 adapted to the cervical os for use in determining cervical dilation during labor.

117. The spherical-shaped integrated circuit of Claim 101 adapted to a needle.

118. The spherical-shaped integrated circuit of Claim 101 adapted to a stylet.

119. The spherical-shaped integrated circuit of Claim 101 adapted to a guidewire.

120. The spherical-shaped integrated circuit of Claim 101 comprising a sensor, a power coil, a power regulator, a processor and electronics including a transmitter.

FIG. 1

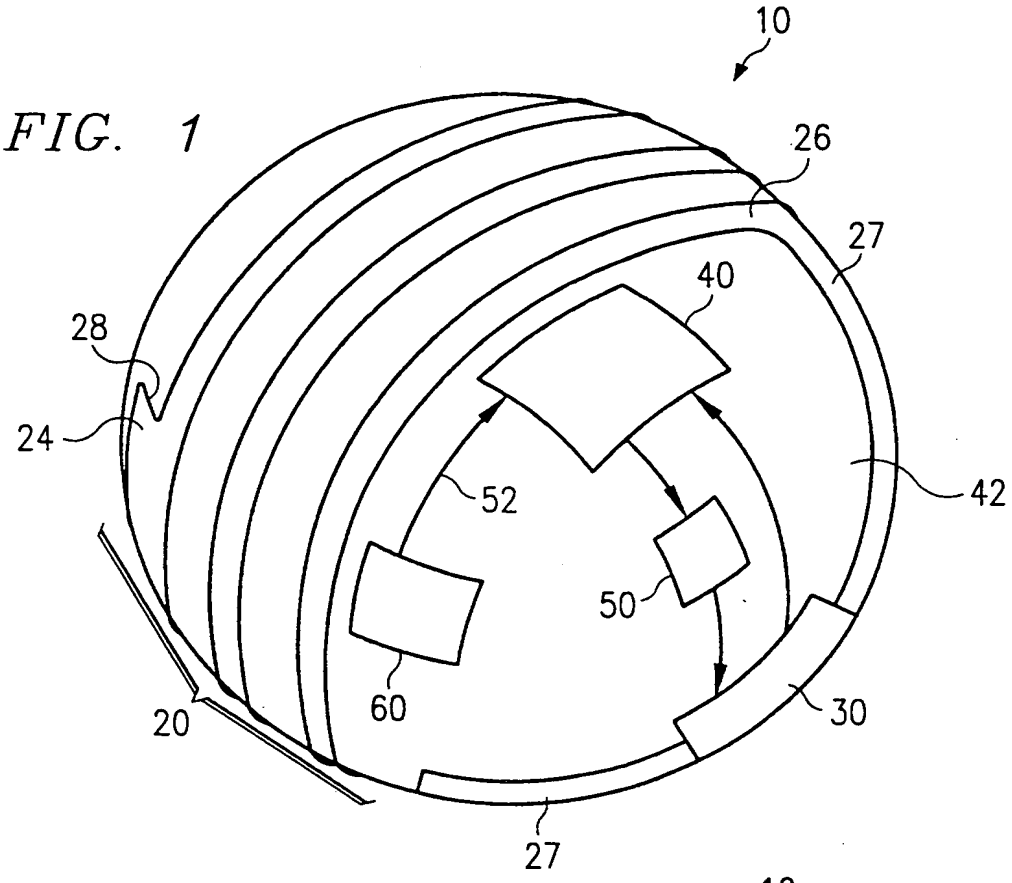
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FIG. 3

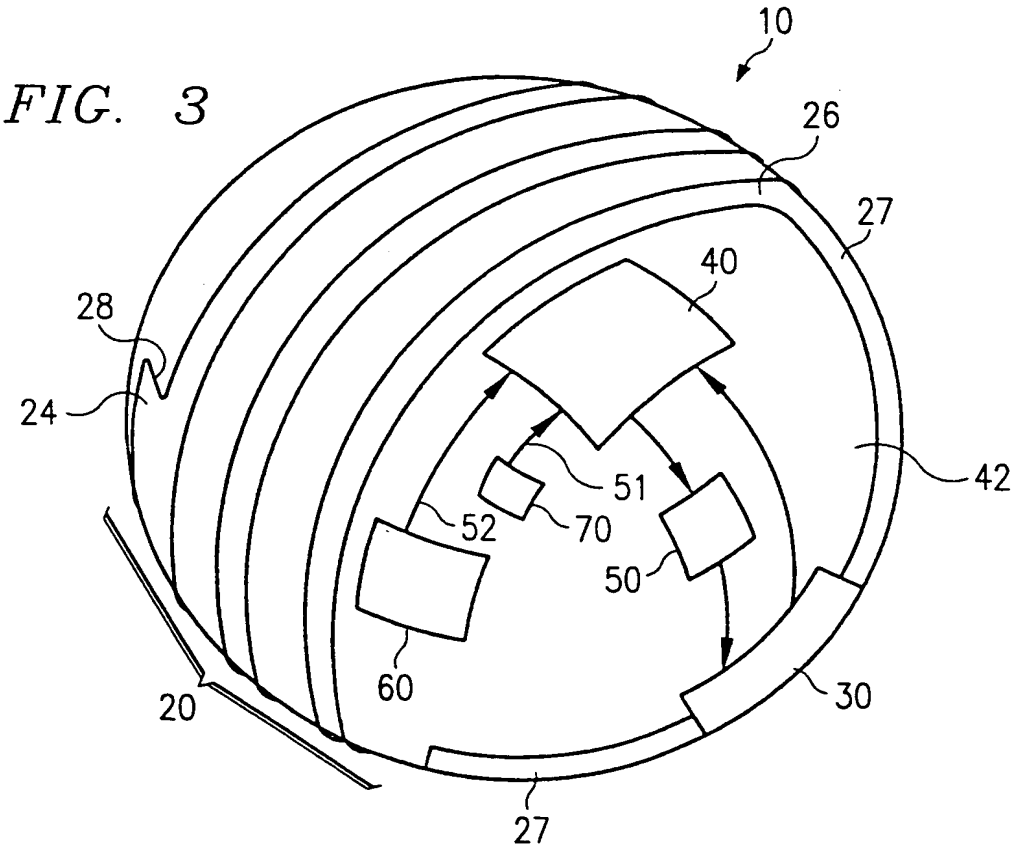
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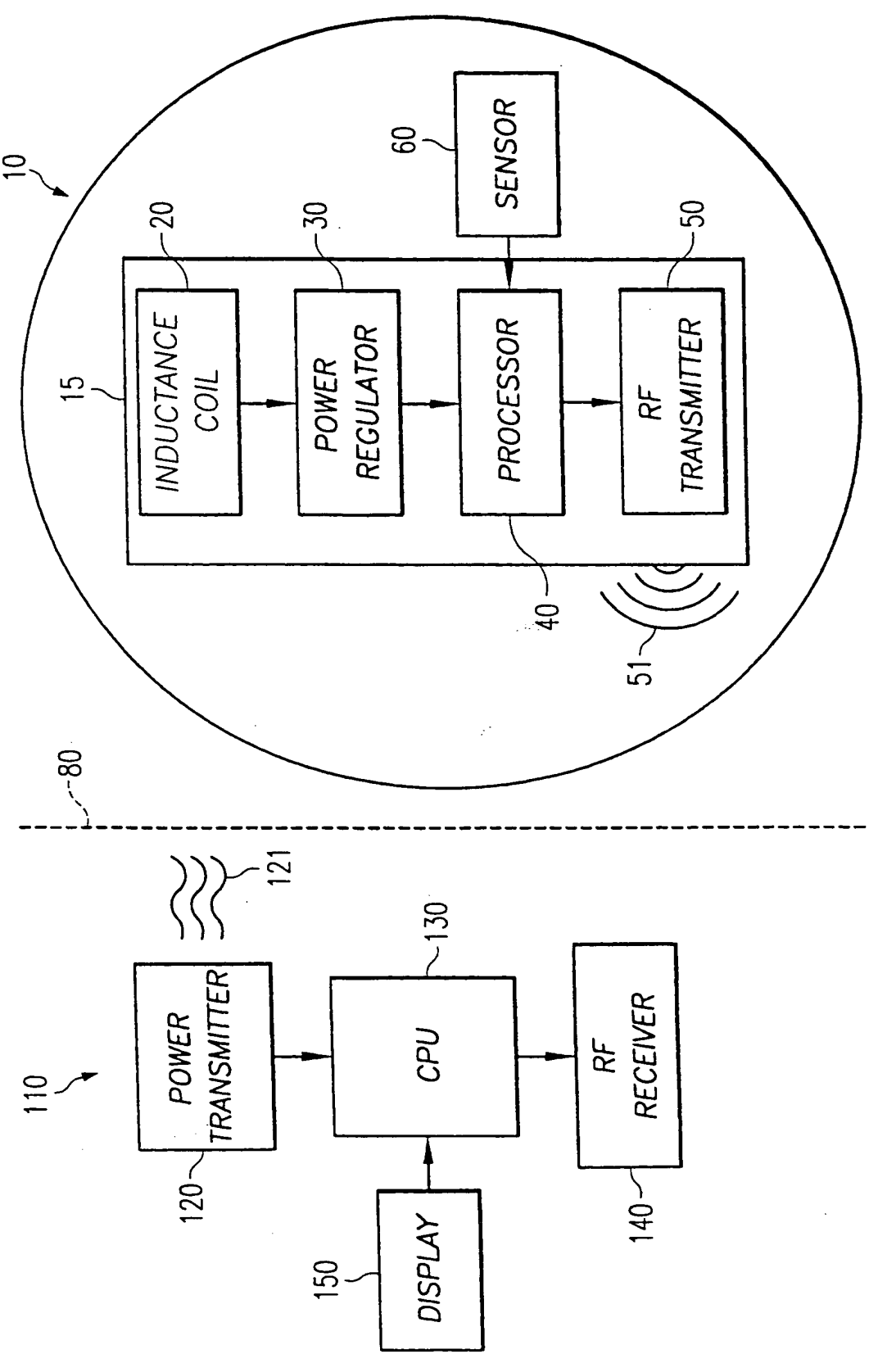
FIG. 2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CPU
RF RECEIVER
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DISPLAY
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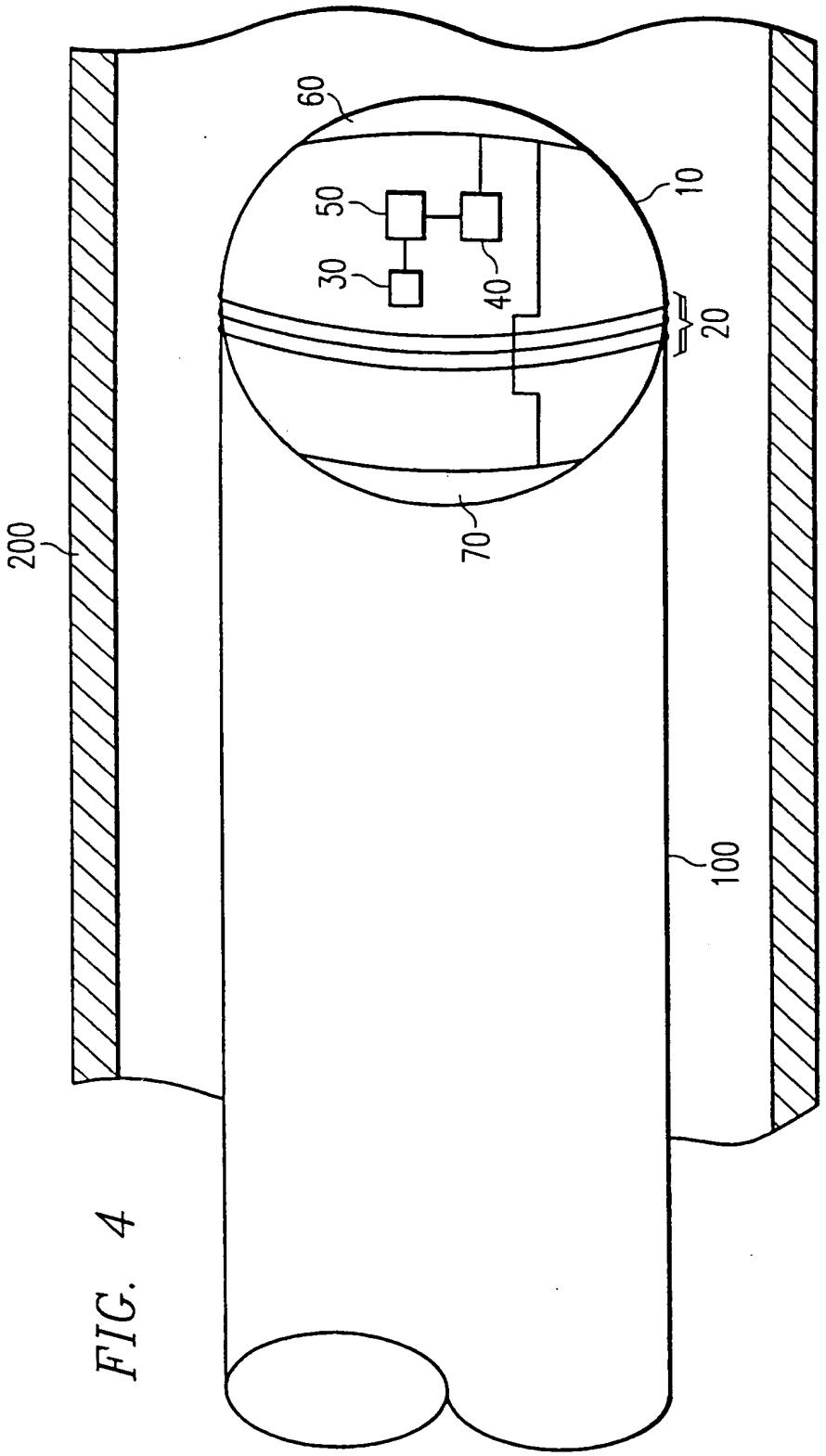
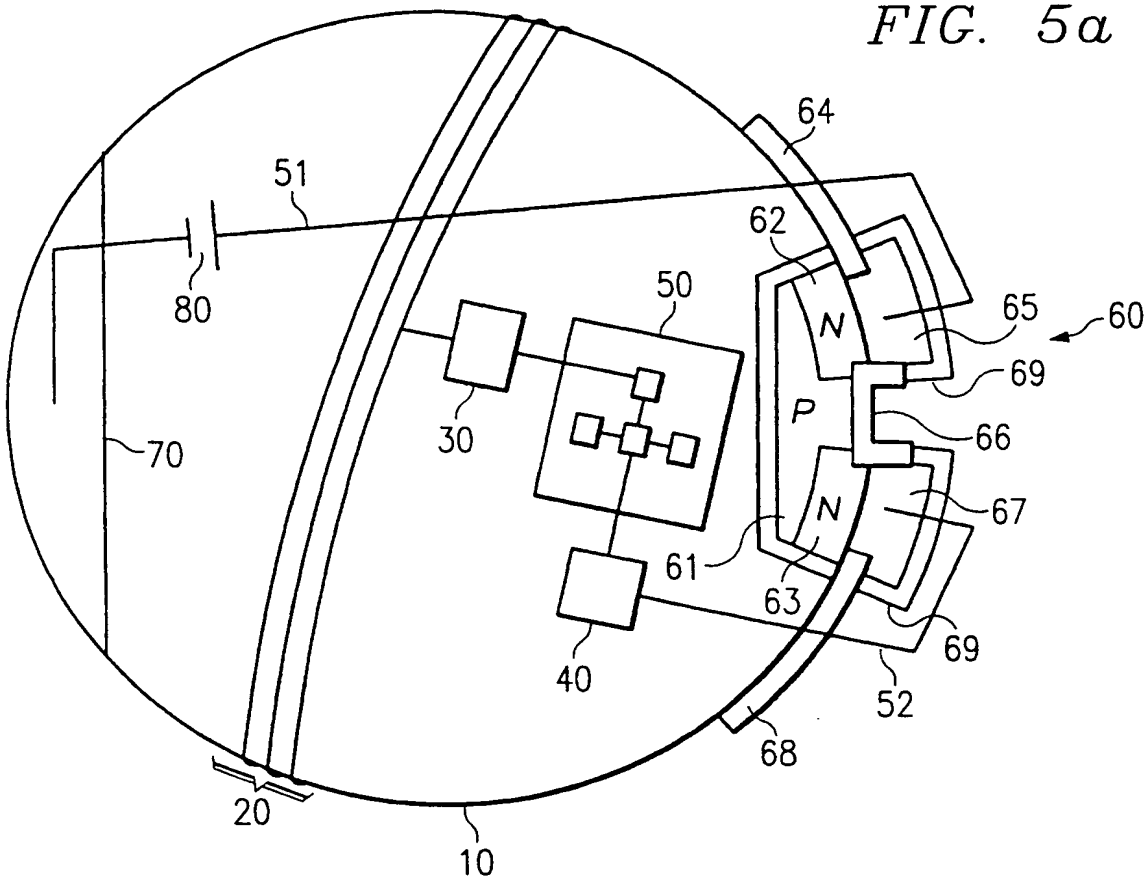


FIG. 4

FIG. 5a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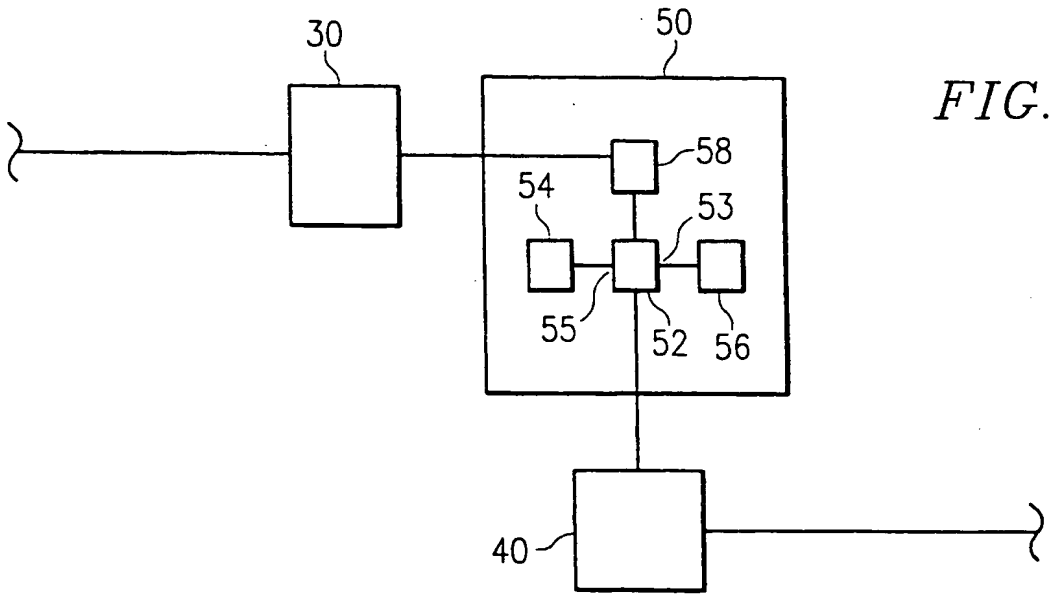
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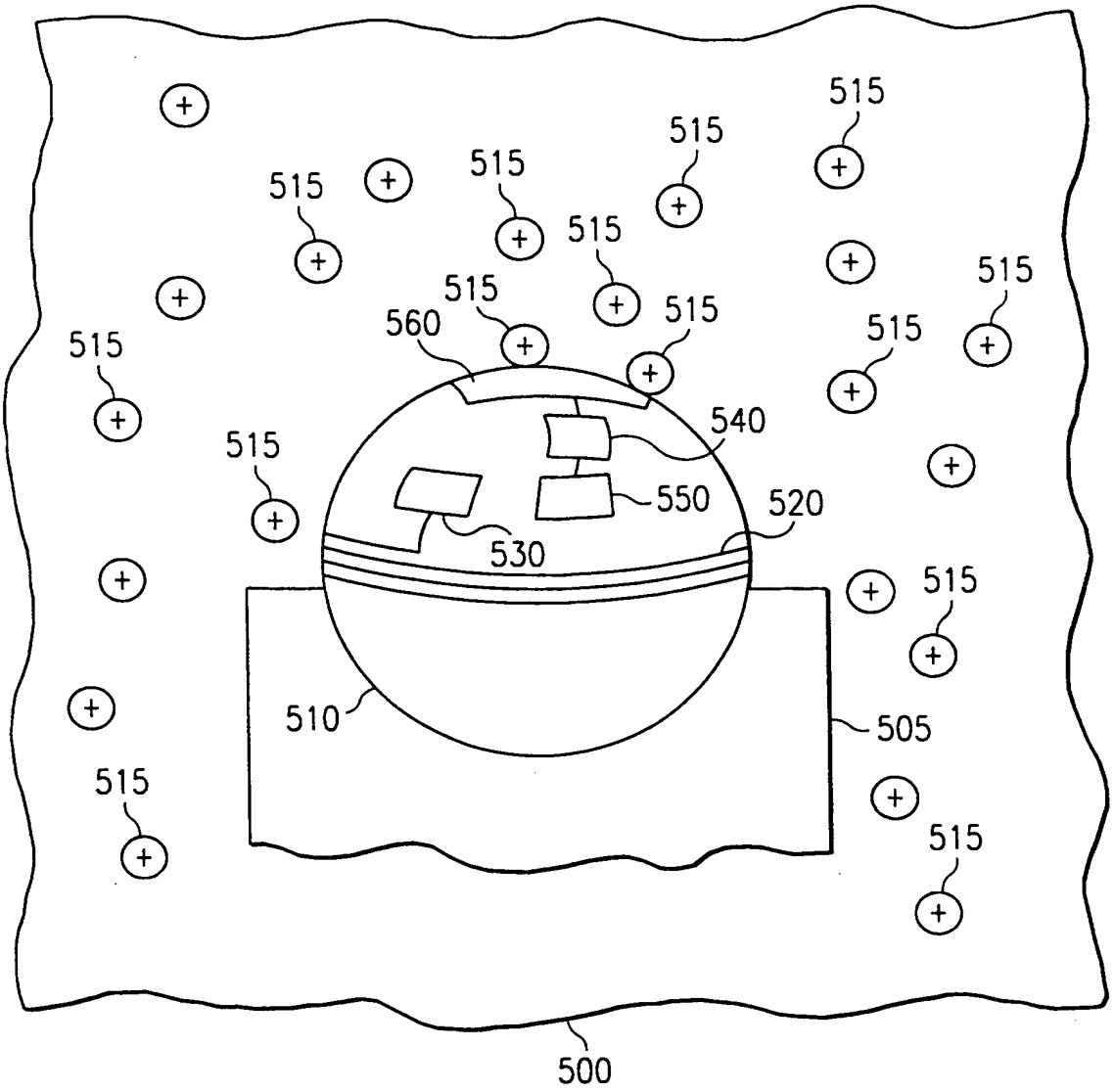
FIG. 5b

FIG. 5c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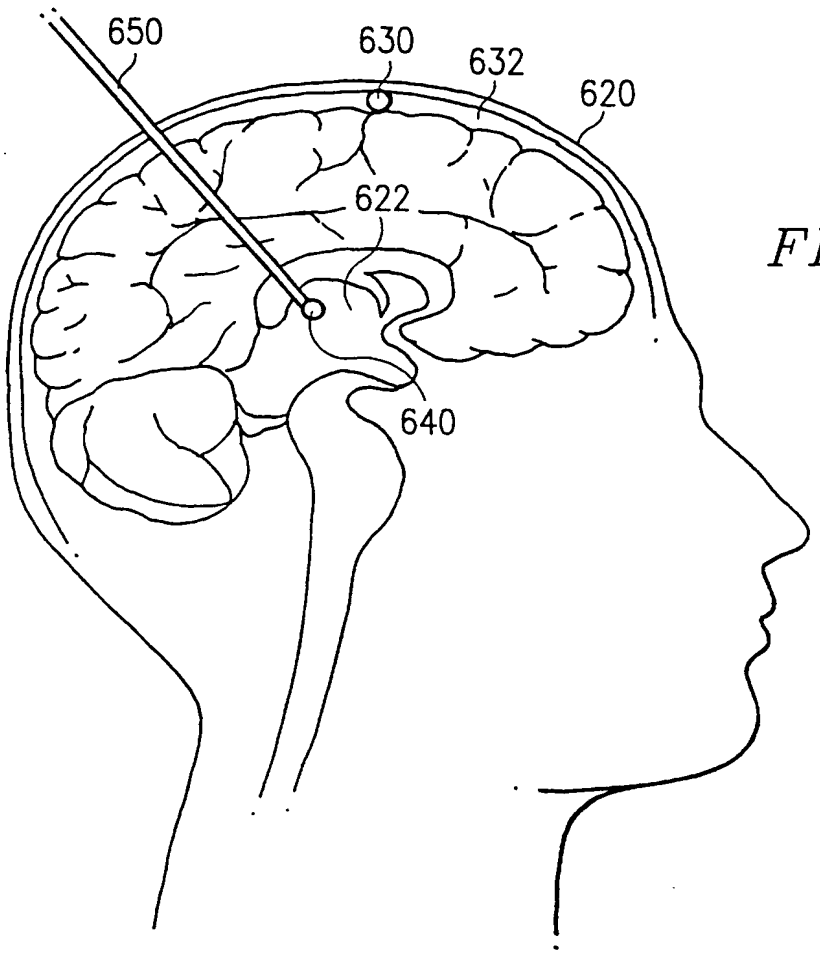


FIG. 6

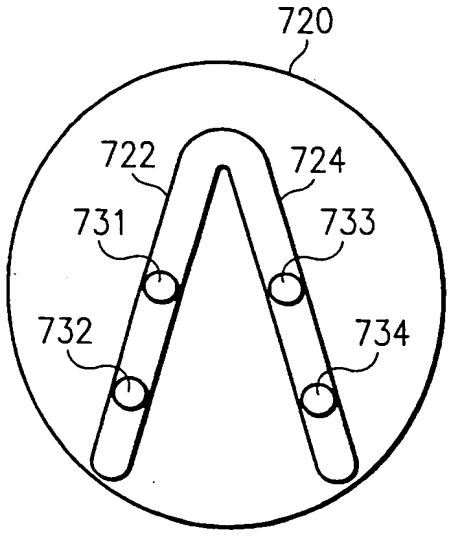


FIG. 7

FIG. 8

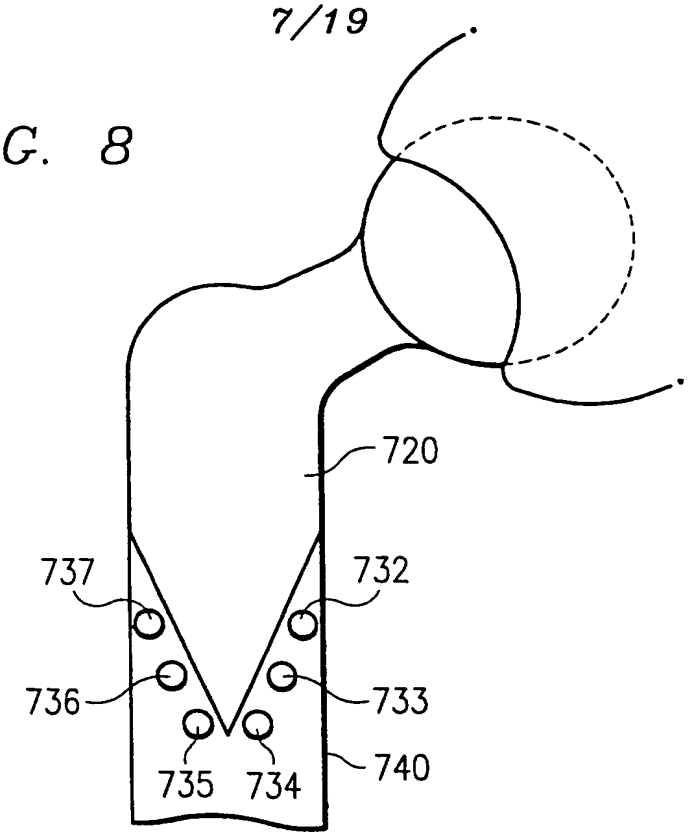
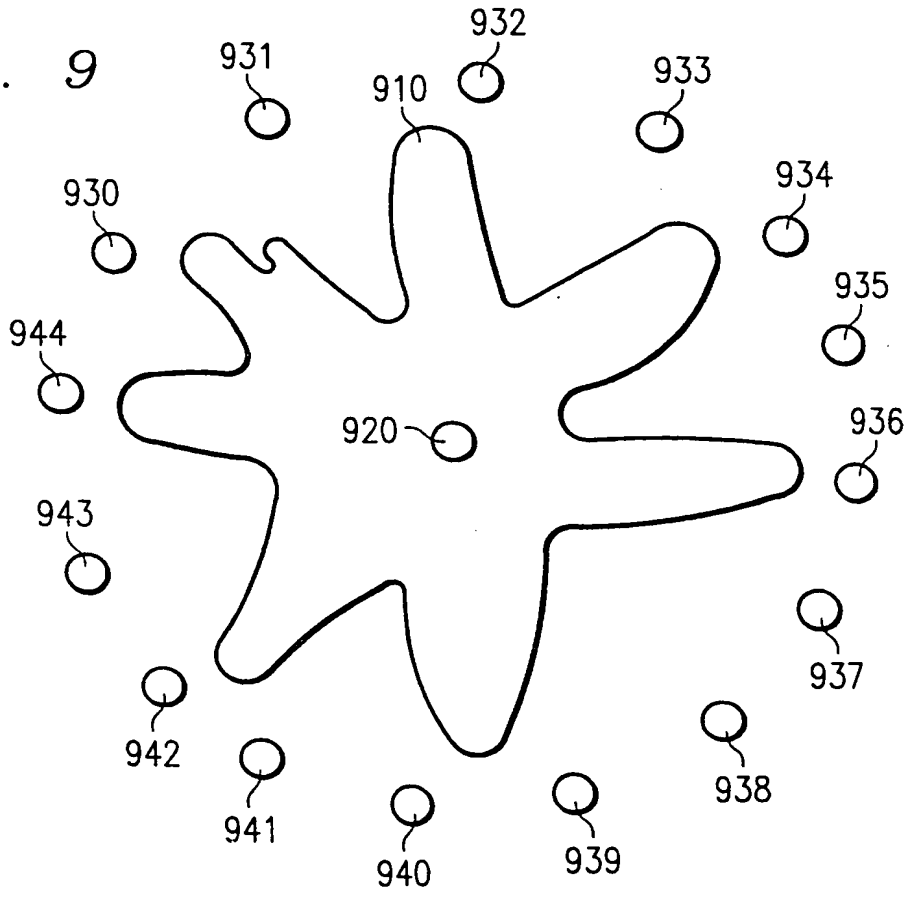

720
737
732
736
733
735
734
740

FIG. 9


931
932
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937
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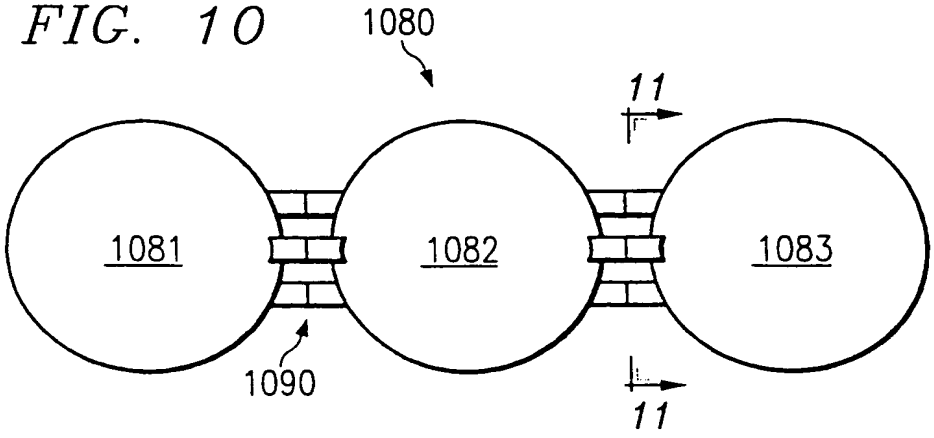
941
940
939

FIG. 10



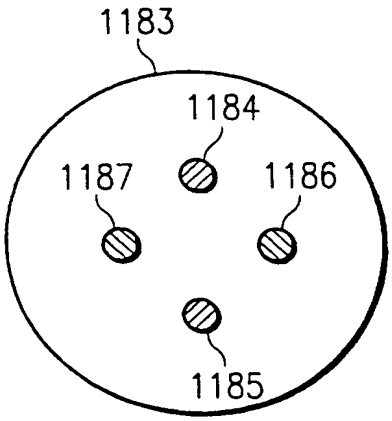


FIG. 11

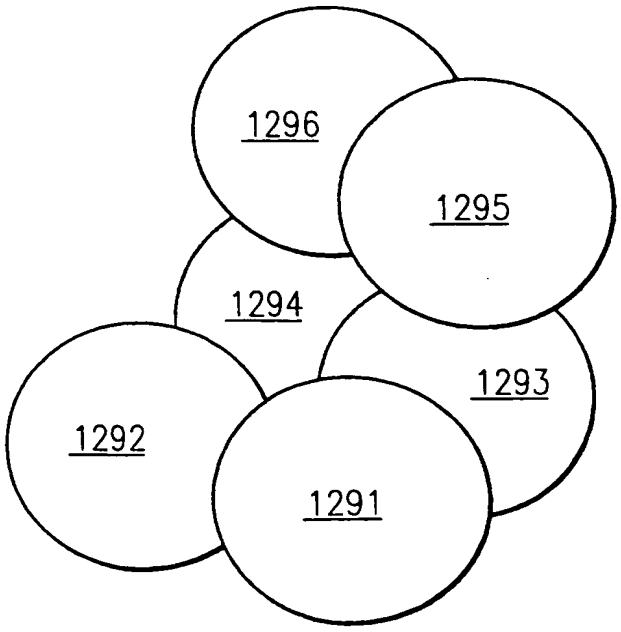
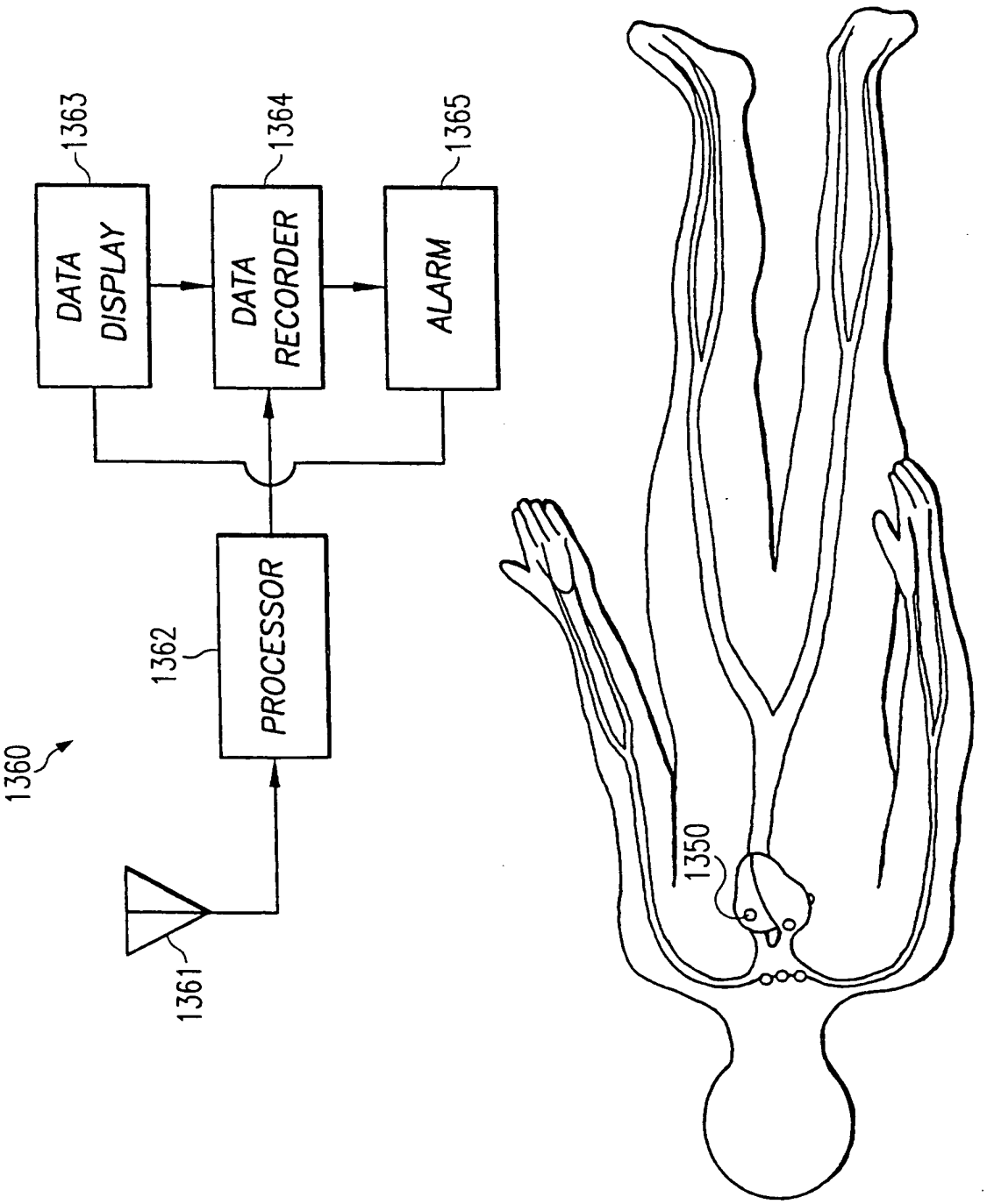
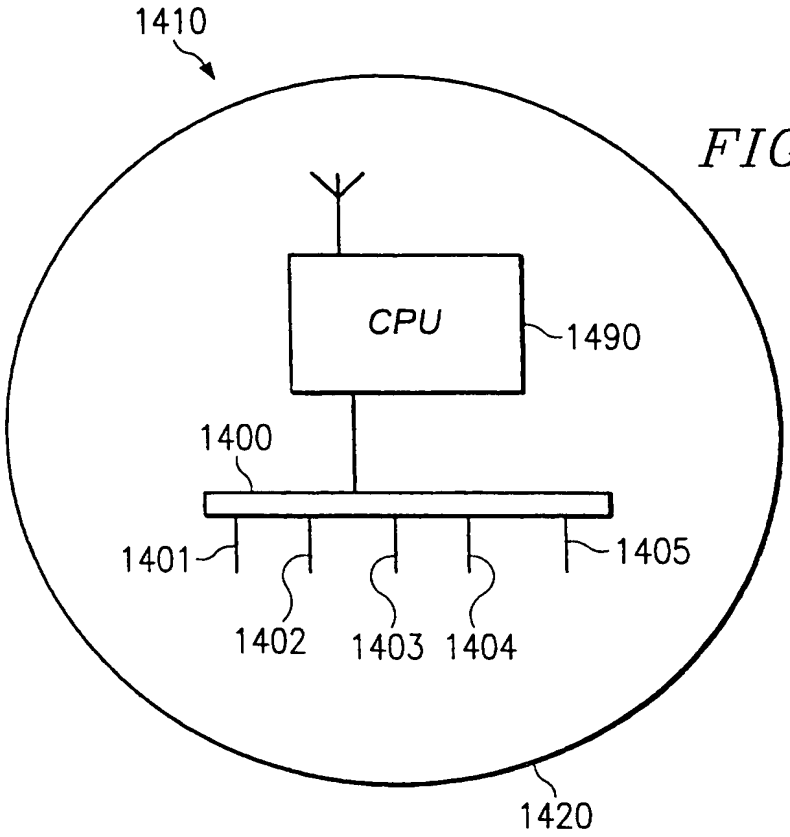


FIG. 12

FIG. 13

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CPU
1490
1400
1401
1405
1402
1403
1404
1420

FIG. 14

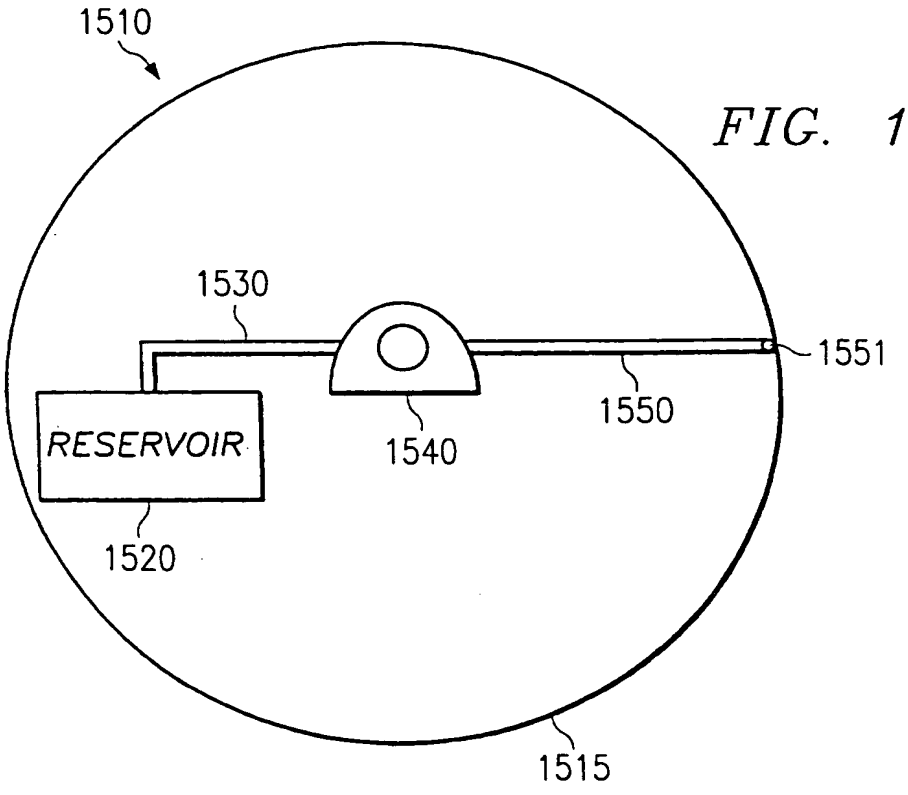

1510
1530
1551
1550
RESERVOIR
1540
1520
1515

FIG. 15

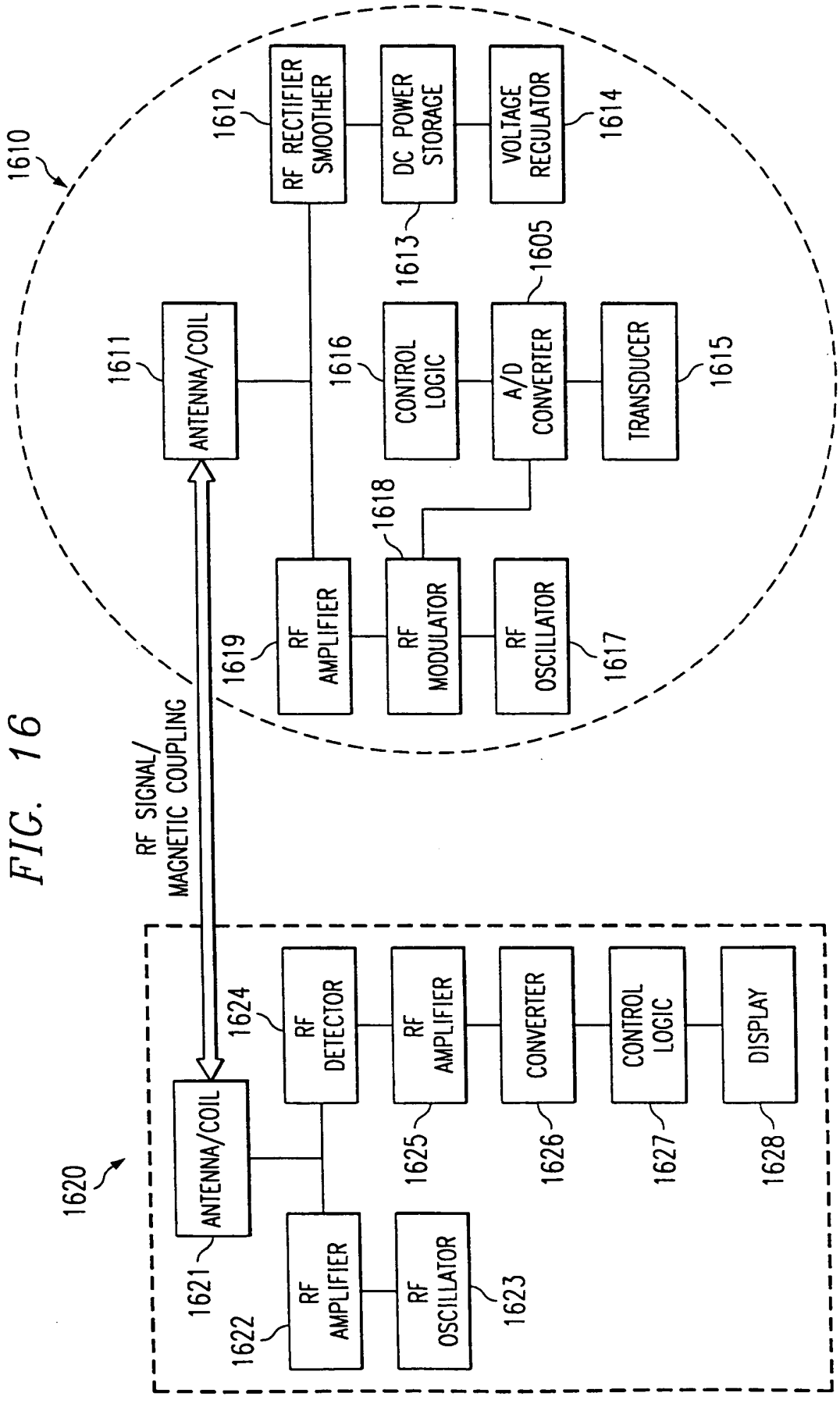
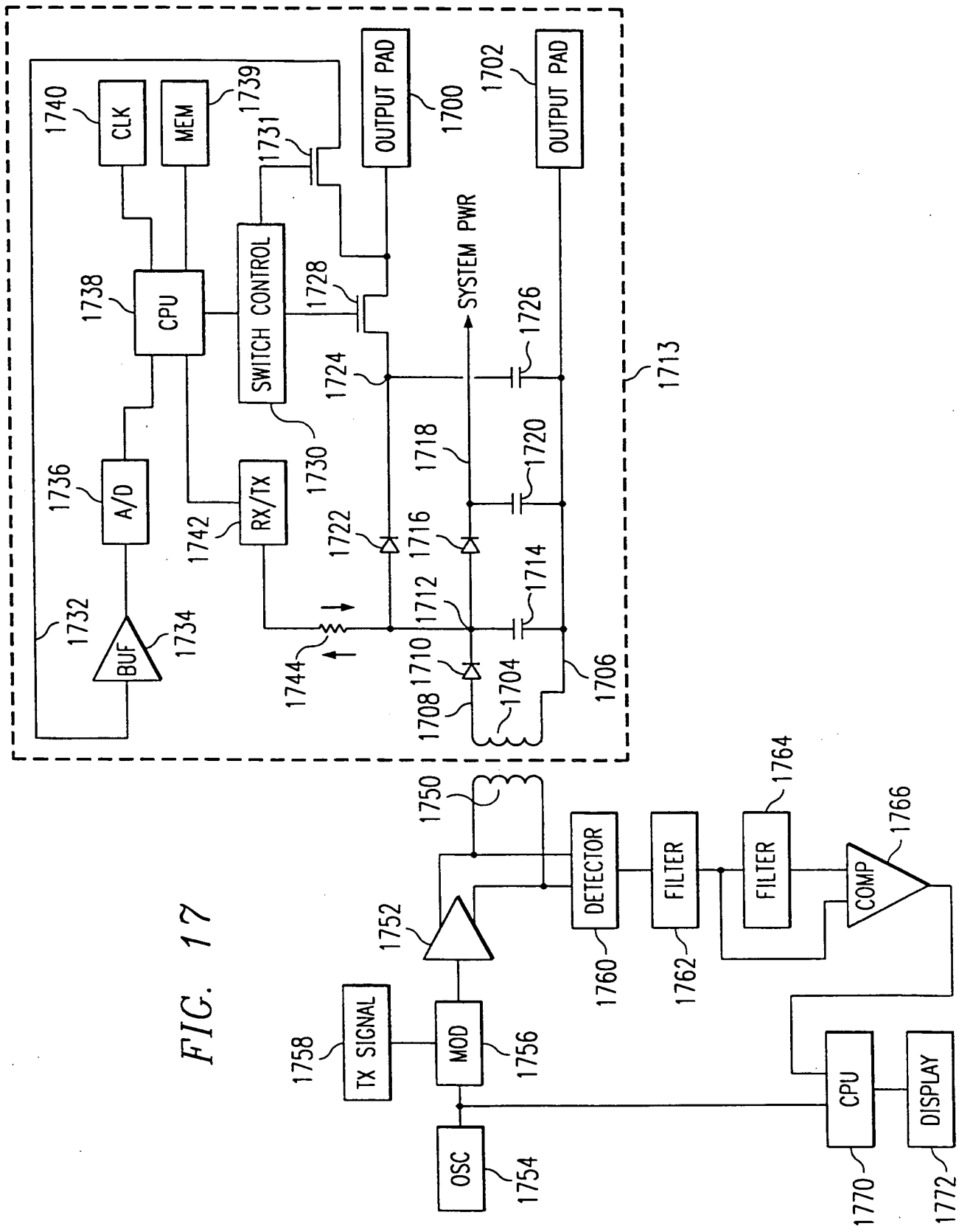

1610
1612
RF RECTIFIER SMOOTHER
DC POWER STORAGE
VOLTAGE REGULATOR
1614
1613
1605
1611
ANTENNA/COIL
1616
CONTROL LOGIC
A/D CONVERTER
TRANSDUCER
1615
1618
RF AMPLIFIER
RF MODULATOR
RF OSCILLATOR
1619
1617
RF SIGNAL/ MAGNETIC COUPLING
1620
ANTENNA/COIL
1621
1624
RF DETECTOR
RF AMPLIFIER
CONVERTER
CONTROL LOGIC
DISPLAY
1625
1626
1627
1628
1622
RF AMPLIFIER
RF OSCILLATOR
1623

FIG. 16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CLK
MEM
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1731
OUTPUT PAD
1700
1702
OUTPUT PAD
1738
CPU
SWITCH CONTROL
1728
SYSTEM PWR
1726
1724
1713
1736
A/D
1730
1718
1720
1742
RX/TX
1722
1716
1732
1734
BUF
1712
1714
1744
1710
1704
1706
1708
1750
1764
1766
DETECTOR
FILTER
FILTER
COMP
1752
1760
1762
1758
TX SIGNAL
MOD
1756
CPU
DISPLAY
OSC
1754
1770
1772

FIG. 17

FIG. 18a

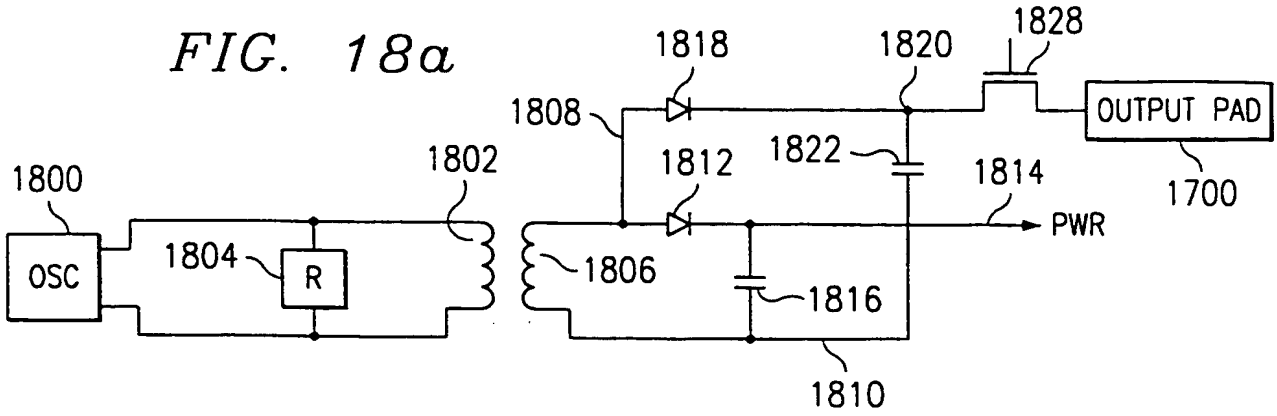


FIG. 18b

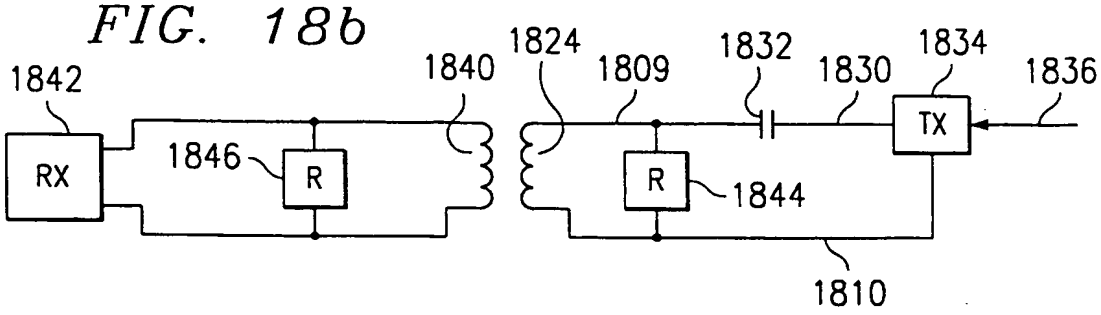


FIG. 18c

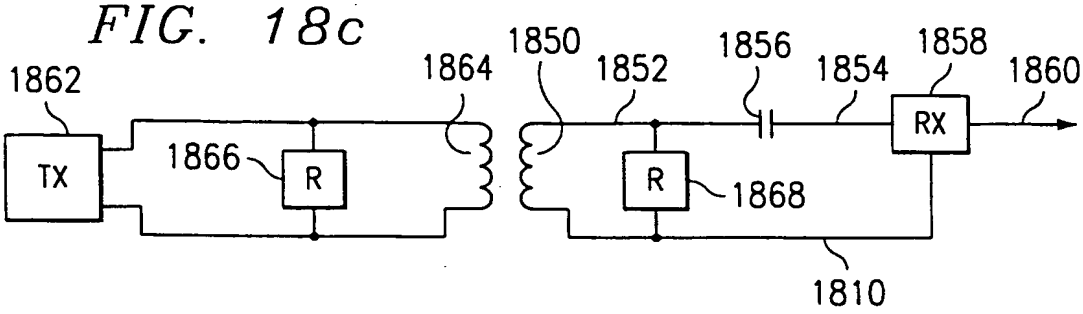


FIG. 19

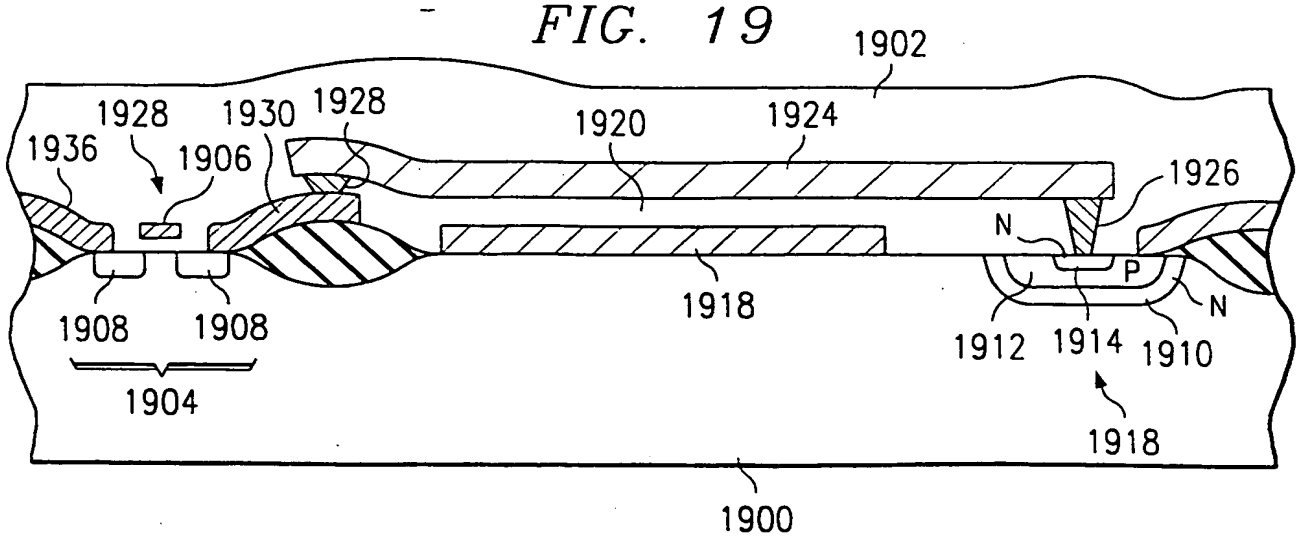


FIG. 20

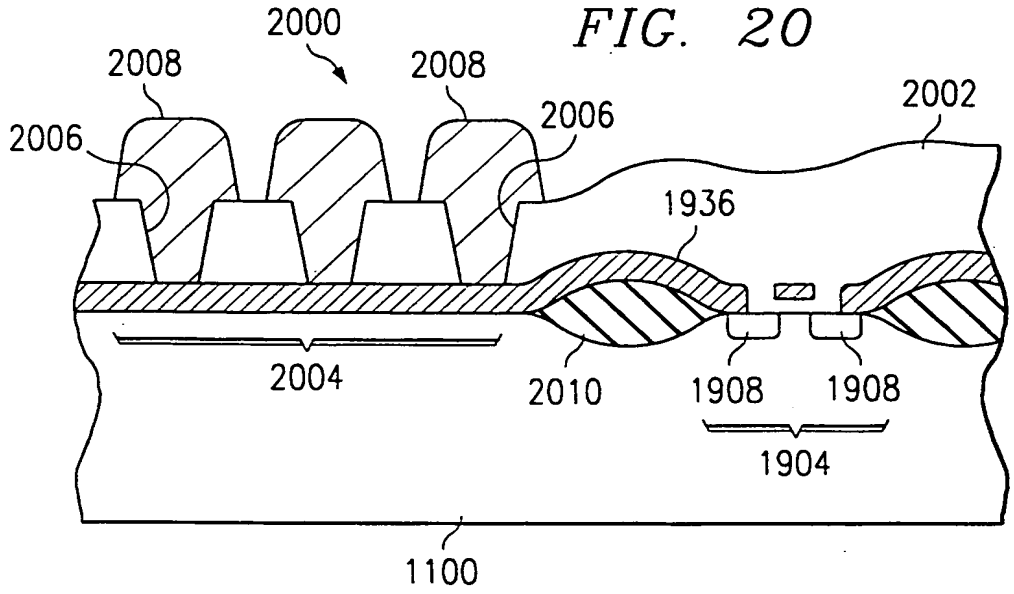


FIG. 21

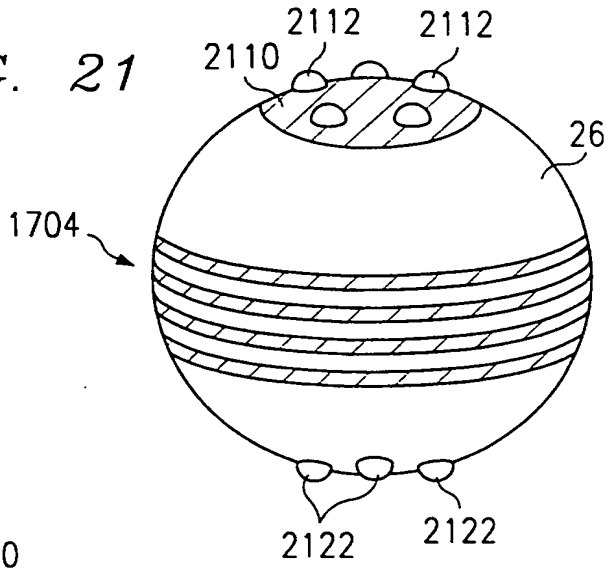


FIG. 22

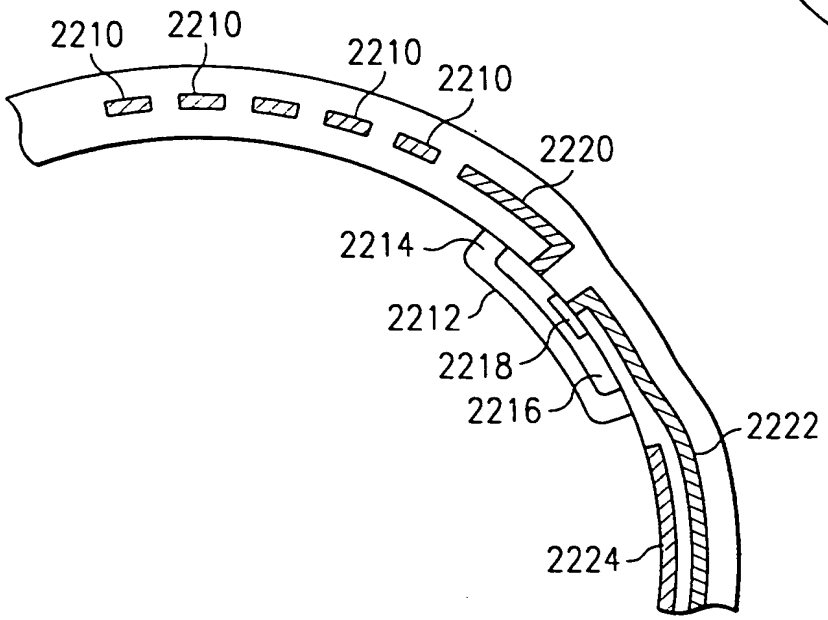
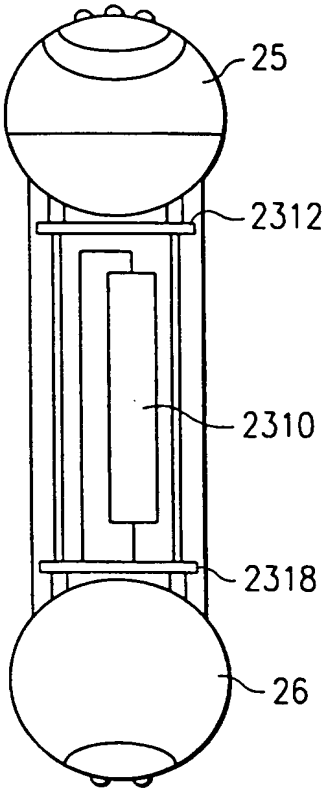


FIG. 23



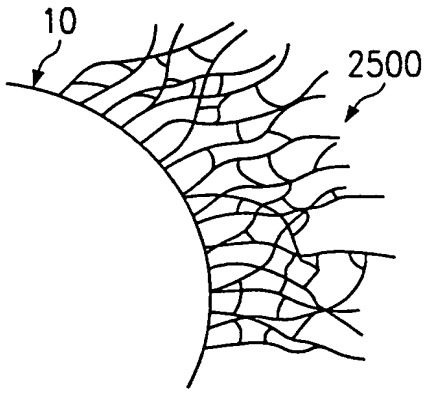
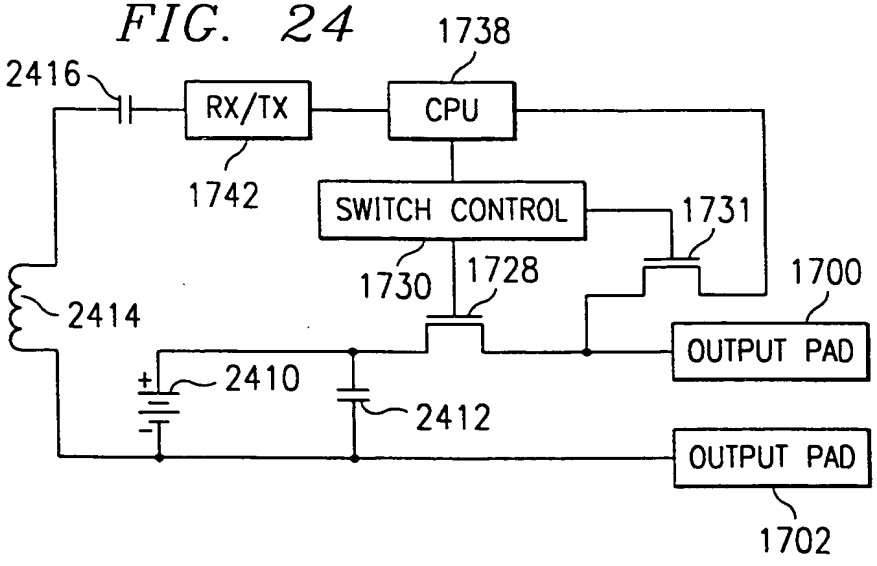


FIG. 25

FIG. 24



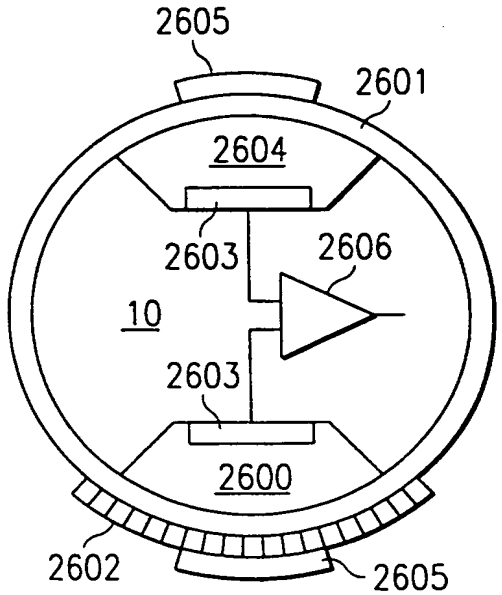


FIG. 26

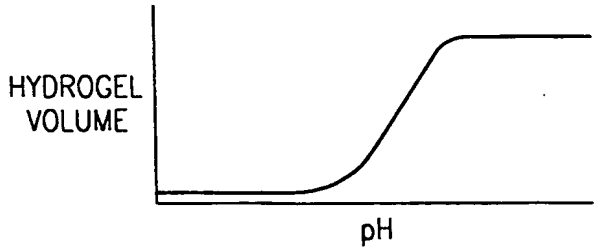


FIG. 27

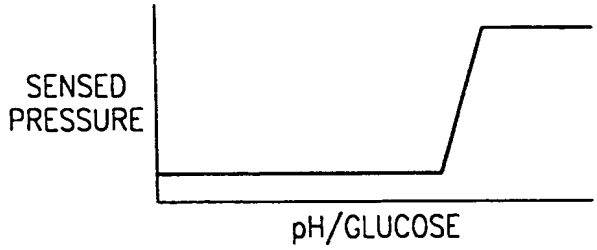


FIG. 28

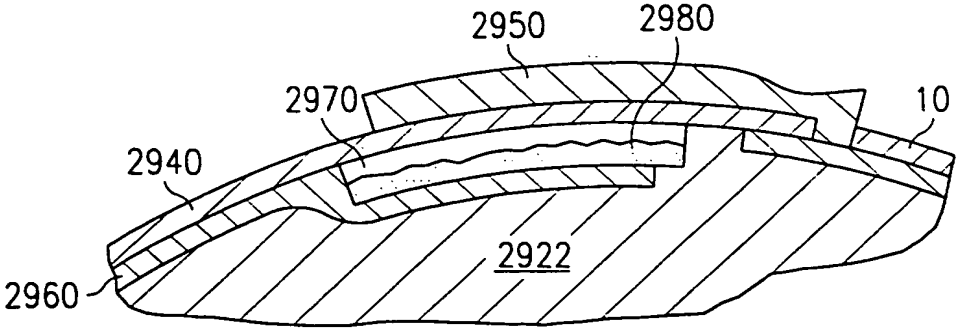


FIG. 29

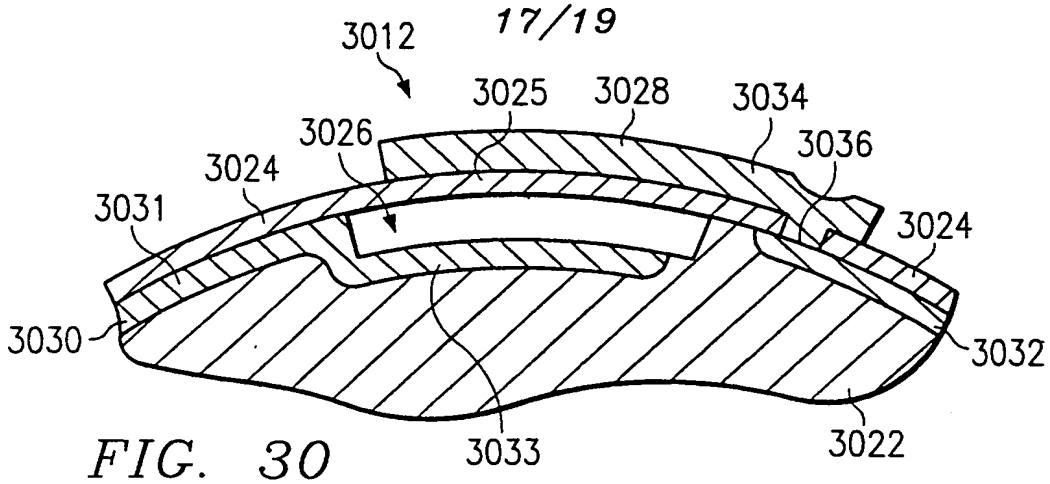
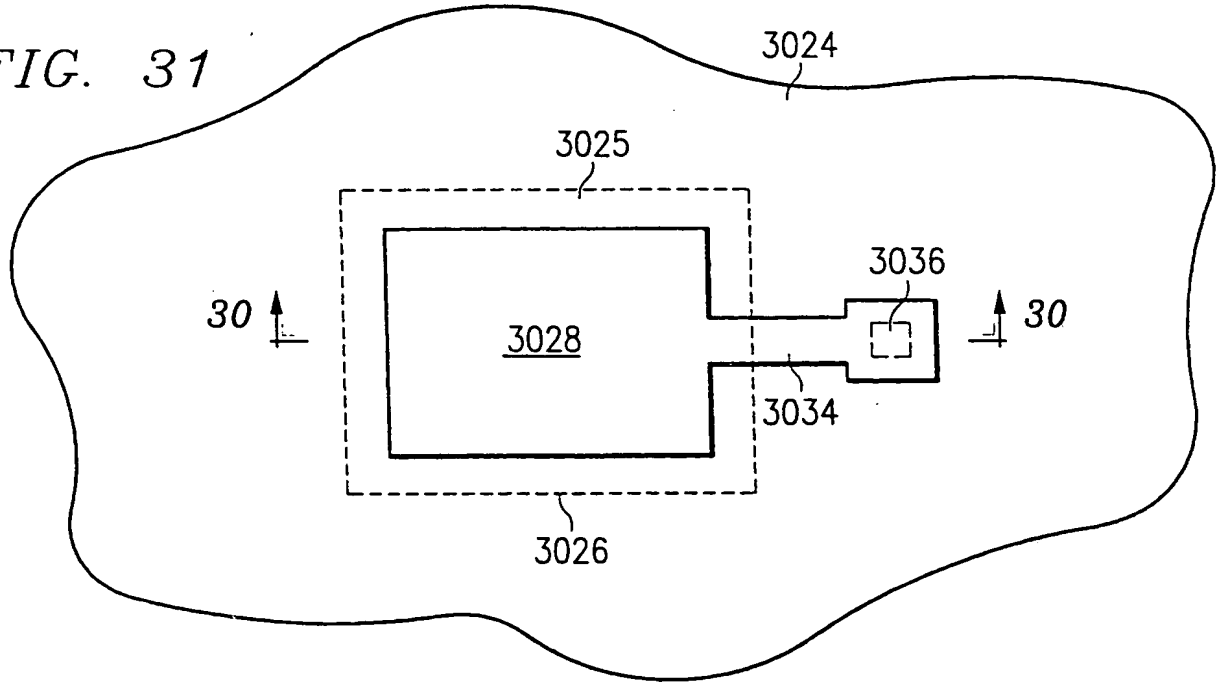


FIG. 30

FIG. 31



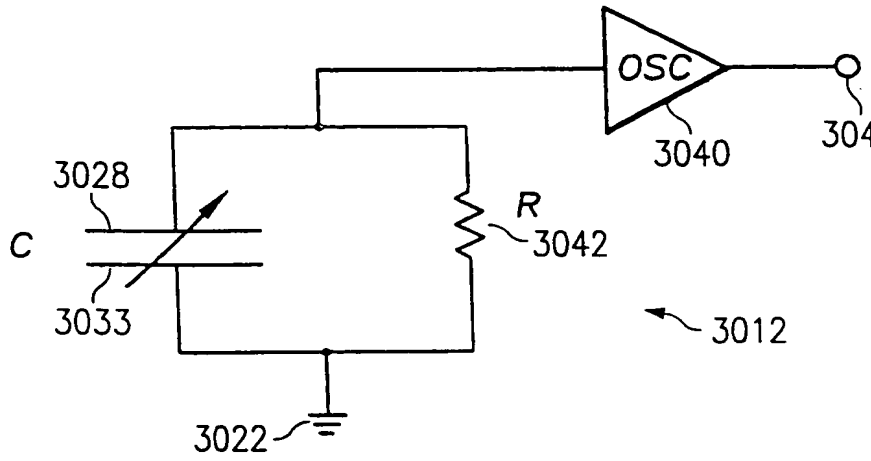


FIG. 32

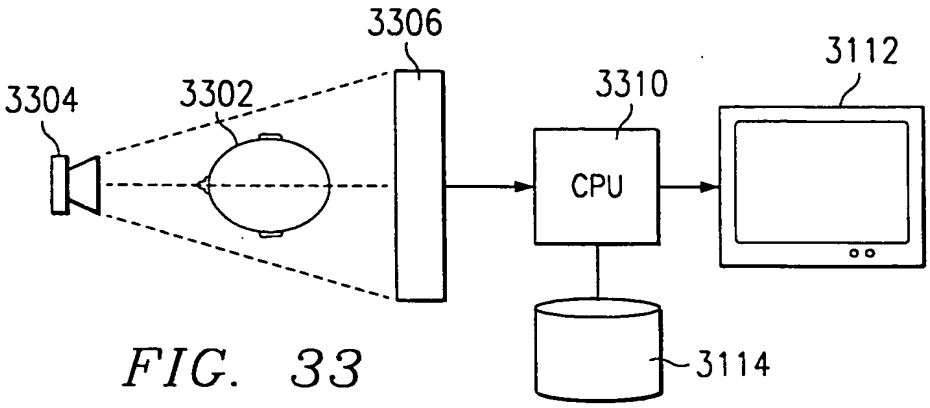


FIG. 33

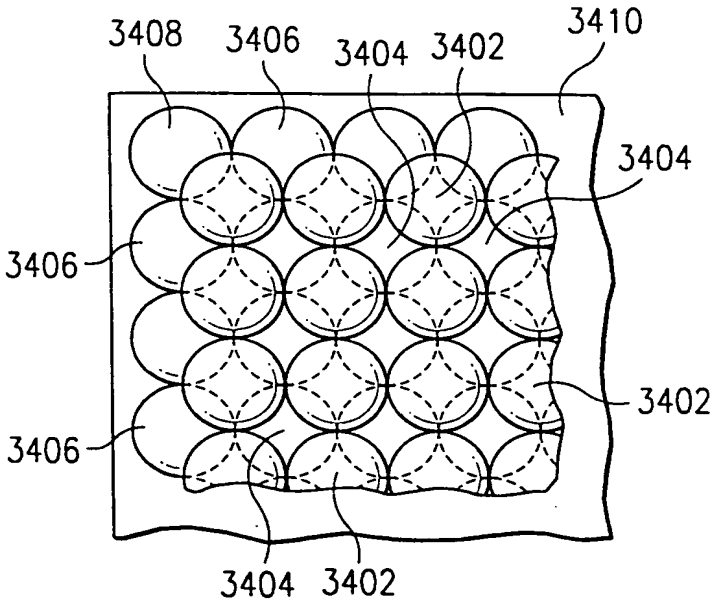


FIG. 34

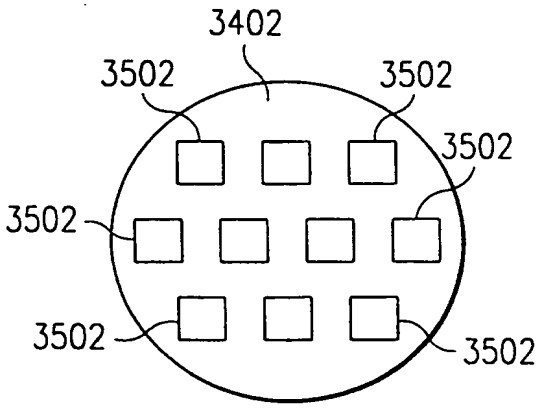


FIG. 35a

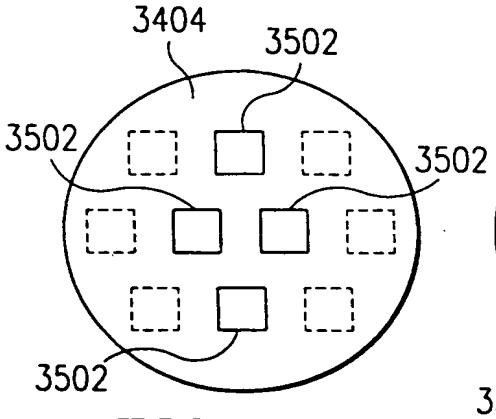


FIG. 35b

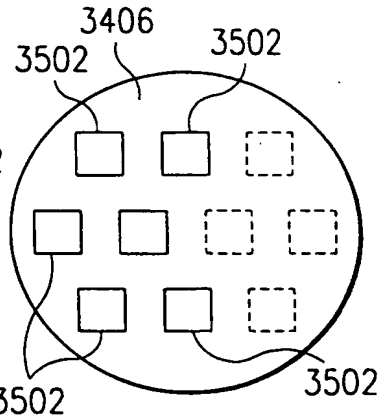


FIG. 35c

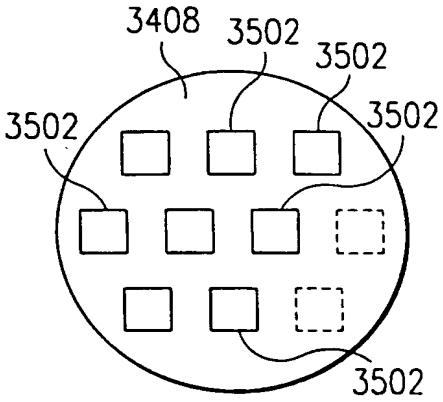


FIG. 35d

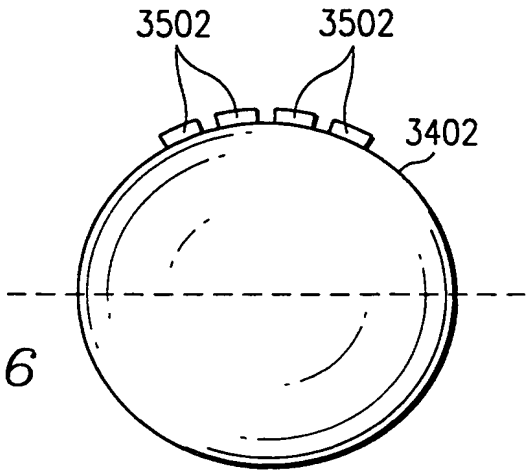


FIG. 36

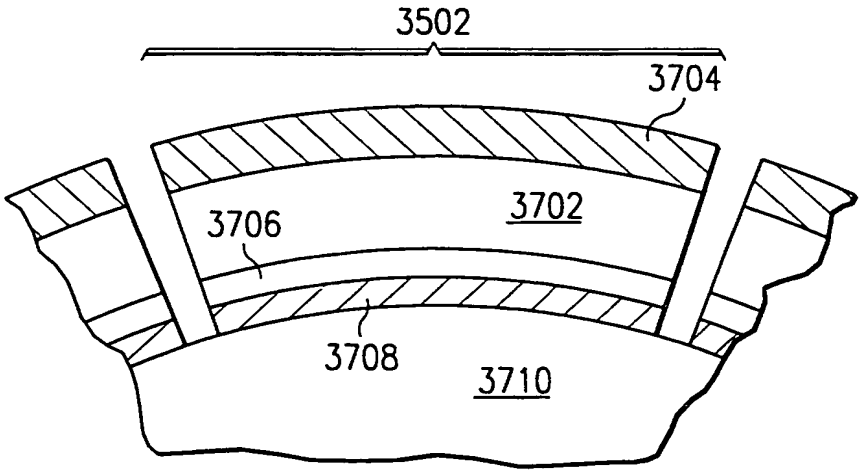


FIG. 37

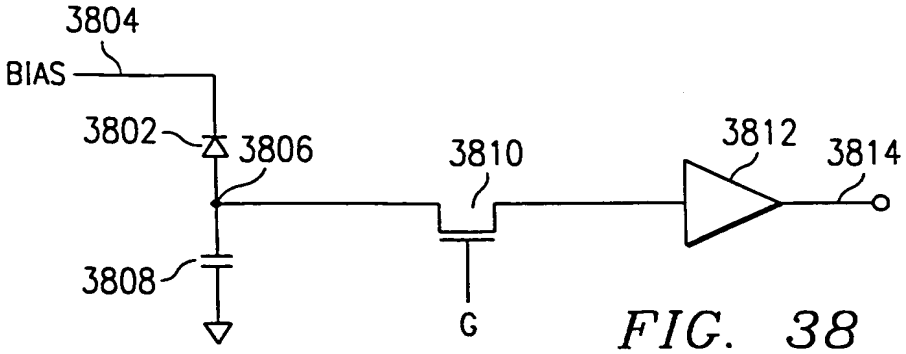


FIG. 38

INTERNATIONAL SEARCH REPORT

Inten nal Application No
PCT/US 99/27904

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	URBAN G A ET AL: "DEVELOPMENT OF A MULTIPLE THIN-FILM SEMIMICRO DC-PROBE FOR INTRACEREBRAL RECORDINGS" IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING,US,IEEE INC. NEW YORK, vol. 37, no. 10, 1 October 1990 (1990-10-01), pages 913-918, XP000171795 ISSN: 0018-9294 sections "INTRODUCTION" and "DESIGN OF THE SURGICAL PROBE"	1,9,17, 98,101

☐ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 March 2000	31/03/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Knüpling, M

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